

## Union Calendar No. 348

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 5651

[Report No. 112-495]

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

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### IN THE HOUSE OF REPRESENTATIVES

MAY 9, 2012

Mr. UPTON (for himself, Mr. WAXMAN, Mr. PITTS, Mr. PALLONE, Mr. BARTON of Texas, and Mr. DINGELL) introduced the following bill; which was referred to the Committee on Energy and Commerce

MAY 25, 2012

Committed to the Committee of the Whole House on the State of the Union  
and ordered to be printed

# **A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

4        This Act may be cited as the “Food and Drug Ad-  
5    ministration Reform Act of 2012”.

7      The table of contents of this Act is as follows:

## TITLE I—FEES RELATING TO DRUGS

TITLE II—MEDICAL DEVICE USER FEE AMENDMENTS OF 2012

### TITLE III—FEES RELATING TO GENERIC DRUGS

## TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

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- Sec. 403. Reauthorization; reporting requirements.
- Sec. 404. Sunset dates.
- Sec. 405. Effective date.
- Sec. 406. Savings clause.
- Sec. 407. Conforming amendment.

#### TITLE V—REAUTHORIZATION OF BEST PHARMACEUTICALS FOR CHILDREN ACT AND PEDIATRIC RESEARCH EQUITY ACT

- Sec. 501. Permanent extension of Best Pharmaceuticals for Children Act and Pediatric Research Equity Act.
- Sec. 502. Food and Drug Administration Report.
- Sec. 503. Internal Committee for Review of Pediatric Plans, Assessments, Deferrals, Deferral Extensions, and Waivers.
- Sec. 504. Staff of Office of Pediatric Therapeutics.
- Sec. 505. Continuation of operation of Pediatric Advisory Committee.
- Sec. 506. Pediatric Subcommittee of the Oncologic Drugs Advisory Committee.

#### TITLE VI—FOOD AND DRUG ADMINISTRATION ADMINISTRATIVE REFORMS

- Sec. 601. Public participation in issuance of FDA guidance documents.
- Sec. 602. Conflicts of interest.
- Sec. 603. Electronic submission of applications.
- Sec. 604. Notification of FDA intent to regulate laboratory-developed tests.

#### TITLE VII—MEDICAL DEVICE REGULATORY IMPROVEMENTS

##### Subtitle A—Premarket Predictability

- Sec. 701. Investigational device exemptions.
- Sec. 702. Clarification of least burdensome standard.
- Sec. 703. Agency documentation and review of significant decisions.
- Sec. 704. Transparency in clearance process.
- Sec. 705. Device Modifications Requiring Premarket Notification Prior to Marketing.

##### Subtitle B—Patients Come First

- Sec. 711. Establishment of schedule and promulgation of regulation.
- Sec. 712. Program to improve the device recall system.

##### Subtitle C—Novel Device Regulatory Relief

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##### Subtitle D—Keeping America Competitive Through Harmonization

- Sec. 731. Harmonization of device premarket review, inspection, and labeling symbols; report.
- Sec. 732. Participation in international fora.

##### Subtitle E—FDA Renewing Efficiency From Outside Reviewer Management

- Sec. 741. Reauthorization of Third Party Review.
- Sec. 742. Reauthorization of third party inspection.

##### Subtitle F—Humanitarian Device Reform

Sec. 751. Expanded access to humanitarian use devices.

#### Subtitle G—Records and Reports on Devices

Sec. 761. Unique device identification system regulations.

Sec. 762. Effective device sentinel program.

#### Subtitle H—Miscellaneous

Sec. 771. Custom devices.

Sec. 772. Pediatric device reauthorization.

Sec. 773. Report on regulation of health information technology.

### TITLE VIII—DRUG REGULATORY IMPROVEMENTS

#### Subtitle A—Drug Supply Chain

Sec. 801. Registration of producers of drugs.

Sec. 802. Inspection of drugs.

Sec. 803. Drug supply quality and safety.

Sec. 804. Prohibition against delaying, denying, limiting, or refusing inspection.

Sec. 805. Destruction of adulterated, misbranded, or counterfeit drugs offered for import.

Sec. 806. Administrative detention.

Sec. 807. Enhanced criminal penalty for counterfeit drugs.

Sec. 808. Unique facility identification number.

Sec. 809. Documentation for admissibility of imports.

Sec. 810. Registration of commercial importers.

Sec. 811. Notification.

Sec. 812. Exchange of information.

Sec. 813. Extraterritorial jurisdiction.

Sec. 814. Protection against intentional adulteration.

Sec. 815. Records for inspection.

#### Subtitle B—Medical Gas Safety

Sec. 821. Regulation of medical gases.

Sec. 822. Changes to regulations.

Sec. 823. Rules of construction.

#### Subtitle C—Generating Antibiotic Incentives Now

Sec. 831. Extension of exclusivity period for drugs.

Sec. 832. Study on incentives for qualified infectious disease biological products.

Sec. 833. Clinical trials.

Sec. 834. Reassessment of qualified infectious disease product incentives in 5 years.

Sec. 835. Guidance on pathogen-focused antibacterial drug development.

#### Subtitle D—Accelerated Approval

Sec. 841. Expedited approval of drugs for serious or life-threatening diseases or conditions.

Sec. 842. Guidance; amended regulations.

Sec. 843. Independent review.

#### Subtitle E—Critical Path Reauthorization

Sec. 851. Reauthorization of the critical path public-private partnerships.

#### Subtitle F—Miscellaneous

Sec. 861. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.

Sec. 862. Extension of period for first applicant to obtain tentative approval without forfeiting 180-day exclusivity period.

Sec. 863. Final agency action relating to petitions and civil actions.

Sec. 864. Deadline for determination on certain petitions.

Sec. 865. Rare pediatric disease priority review voucher incentive program.

Sec. 866. Combating prescription drug abuse.

Sec. 867. Assessment and modification of REMS.

Sec. 868. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments.

Sec. 869. Breakthrough therapies.

Sec. 870. Grants and Contracts for the Development of Orphan Drugs.

#### TITLE IX—DRUG SHORTAGES

Sec. 901. Discontinuance and interruptions of manufacturing of certain drugs.

Sec. 902. Drug shortage list.

Sec. 903. Quotas applicable to drugs in shortage.

Sec. 904. Expedited review of major manufacturing changes for potential and verified shortages of drugs that are life-supporting, life-sustaining, or intended for use in the prevention of a debilitating disease or condition.

Sec. 905. Study on drug shortages.

Sec. 906. Annual report on drug shortages.

Sec. 907. Attorney General report on drug shortages.

Sec. 908. Hospital repackaging of drugs in shortage.

#### 1 **SEC. 3. REFERENCES IN ACT.**

2       Except as otherwise specified, amendments made by  
3 this Act to a section or other provision of law are amend-  
4 ments to such section or other provision of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

## 6       **TITLE I—FEES RELATING TO** 7       **DRUGS**

#### 8 **SEC. 101. SHORT TITLE; FINDING.**

9       (a) **SHORT TITLE.**—This title may be cited as the  
10 “Prescription Drug User Fee Amendments of 2012”.

1 (b) FINDING.—The Congress finds that the fees au-  
2 thorized by the amendments made in this title will be dedi-  
3 cated toward expediting the drug development process and  
4 the process for the review of human drug applications, in-  
5 cluding postmarket drug safety activities, as set forth in  
6 the goals identified for purposes of part 2 of subchapter  
7 C of chapter VII of the Federal Food, Drug, and Cosmetic  
8 Act, in the letters from the Secretary of Health and  
9 Human Services to the Chairman of the Committee on  
10 Health, Education, Labor, and Pensions of the Senate and  
11 the Chairman of the Committee on Energy and Commerce  
12 of the House of Representatives, as set forth in the Con-  
13 gressional Record.

14 **SEC. 102. DEFINITIONS.**

15 Section 735(7) (21 U.S.C. 379g) is amended by strik-  
16 ing “expenses incurred in connection with” and inserting  
17 “expenses in connection with”.

18 **SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.**

19 Section 736 (21 U.S.C. 379h) is amended—

20 (1) in subsection (a)—

21 (A) in the matter preceding paragraph (1),  
22 by striking “fiscal year 2008” and inserting  
23 “fiscal year 2013”;

24 (B) in paragraph (1)(A)—

1 (i) in clause (i), by striking “(c)(5)”  
2 inserting “(c)(4)”; and

3 (ii) in clause (ii), by striking “(c)(5)”  
4 inserting “(c)(4)”;

5 (C) in the matter following clause (ii) in  
6 paragraph (2)(A)—

7 (i) by striking “(c)(5)” inserting  
8 “(c)(4)”; and

9 (ii) by striking “payable on or before  
10 October 1 of each year” and inserting  
11 “due on the later of the first business day  
12 on or after October 1 of such fiscal year or  
13 the first business day after the enactment  
14 of an appropriations Act providing for the  
15 collection and obligation of fees for such  
16 fiscal year under this section”;

17 (D) in paragraph (3)—

18 (i) in subparagraph (A)—

19 (I) by striking “subsection  
20 (c)(5)” and inserting “subsection  
21 (c)(4)”; and

22 (II) by striking “payable on or  
23 before October 1 of each year.” and  
24 inserting “due on the later of the first  
25 business day on or after October 1 of



1 each such fiscal year or the first busi-  
2 ness day after the enactment of an  
3 appropriations Act providing for the  
4 collection and obligation of fees for  
5 each such fiscal year under this sec-  
6 tion.”; and

7 (ii) by amending subparagraph (B) to  
8 read as follows:

9 “(B) EXCEPTION.—A prescription drug  
10 product shall not be assessed a fee under sub-  
11 paragraph (A) if such product is—

12 “(i) identified on the list compiled  
13 under section 505(j)(7)(A) with a potency  
14 described in terms of per 100 mL;

15 “(ii) the same product as another  
16 product that—

17 “(I) was approved under an ap-  
18 plication filed under section 505(b) or  
19 505(j); and

20 “(II) is not in the list of discon-  
21 tinued products compiled under sec-  
22 tion 505(j)(7)(A);

23 “(iii) the same product as another  
24 product that was approved under an abbrevi-  
25 ated application filed under section 507

1 (as in effect on the day before the date of  
2 enactment of the Food and Drug Adminis-  
3 tration Modernization Act of 1997); or

4 “(iv) the same product as another  
5 product that was approved under an abbrevi-  
6 ated new drug application pursuant to  
7 regulations in effect prior to the implemen-  
8 tation of the Drug Price Competition and  
9 Patent Term Restoration Act of 1984.”;

10 (2) in subsection (b)—

11 (A) in paragraph (1)—

12 (i) in the language preceding subpara-  
13 graph (A), by striking “fiscal years 2008  
14 through 2012” and inserting “fiscal years  
15 2013 through 2017”; and

16 (ii) in subparagraph (A), by striking  
17 “\$392,783,000; and” and inserting  
18 “\$693,099,000;”; and

19 (iii) by striking subparagraph (B) and  
20 inserting the following:

21 “(B) the dollar amount equal to the infla-  
22 tion adjustment for fiscal year 2013 (as deter-  
23 mined under paragraph (3)(A)); and

1 “(C) the dollar amount equal to the work-  
2 load adjustment for fiscal year 2013 (as deter-  
3 mined under paragraph (3)(B)).”; and

4 (B) by striking paragraphs (3) and (4) and  
5 inserting the following:

6 “(3) FISCAL YEAR 2013 INFLATION AND WORK-  
7 LOAD ADJUSTMENTS.—For purposes of paragraph  
8 (1), the dollar amount of the inflation and workload  
9 adjustments for fiscal year 2013 shall be determined  
10 as follows:

11 “(A) INFLATION ADJUSTMENT.—The infla-  
12 tion adjustment for fiscal year 2013 shall be  
13 the sum of—

14 “(i) \$652,709,000 multiplied by the  
15 result of an inflation adjustment calcula-  
16 tion determined using the methodology de-  
17 scribed in subsection (c)(1)(B); and

18 “(ii) \$652,709,000 multiplied by the  
19 result of an inflation adjustment calcula-  
20 tion determined using the methodology de-  
21 scribed in subsection (c)(1)(C).

22 “(B) WORKLOAD ADJUSTMENT.—Subject  
23 to subparagraph (C), the workload adjustment  
24 for fiscal 2013 shall be—

1 “(i) \$652,709,000 plus the amount of  
2 the inflation adjustment calculated under  
3 subparagraph (A); multiplied by

4 “(ii) the amount (if any) by which a  
5 percentage workload adjustment for fiscal  
6 year 2013, as determined using the meth-  
7 odology described in subsection (c)(2)(A),  
8 would exceed the percentage workload ad-  
9 justment (as so determined) for fiscal year  
10 2012, if both such adjustment percentages  
11 were calculated using the 5-year base pe-  
12 riod consisting of fiscal years 2003  
13 through 2007.

14 “(C) LIMITATION.—Under no cir-  
15 cumstances shall the adjustment under sub-  
16 paragraph (B) result in fee revenues for fiscal  
17 year 2013 that are less than the sum of the  
18 amount under paragraph (1)(A) and the  
19 amount under paragraph (1)(B).”;

20 (3) by striking subsection (c) and inserting the  
21 following:

22 “(c) ADJUSTMENTS.—

23 “(1) INFLATION ADJUSTMENT.—For fiscal year  
24 2014 and subsequent fiscal years, the revenues es-  
25 tablished in subsection (b) shall be adjusted by the

1 Secretary by notice, published in the Federal Reg-  
2 ister, for a fiscal year by the amount equal to the  
3 sum of—

4 “(A) one;

5 “(B) the average annual percent change in  
6 the cost, per full-time equivalent position of the  
7 Food and Drug Administration, of all personnel  
8 compensation and benefits paid with respect to  
9 such positions for the first 3 years of the pre-  
10 ceding 4 fiscal years, multiplied by the propor-  
11 tion of personnel compensation and benefits  
12 costs to total costs of the process for the review  
13 of human drug applications (as defined in sec-  
14 tion 735(6)) for the first 3 years of the pre-  
15 ceding 4 fiscal years, and

16 “(C) the average annual percent change  
17 that occurred in the Consumer Price Index for  
18 urban consumers (Washington-Baltimore, DC–  
19 MD–VA–WV; Not Seasonally Adjusted; All  
20 items; Annual Index) for the first 3 years of the  
21 preceding 4 years of available data multiplied  
22 by the proportion of all costs other than per-  
23 sonnel compensation and benefits costs to total  
24 costs of the process for the review of human  
25 drug applications (as defined in section 735(6))

1           for the first 3 years of the preceding 4 fiscal  
2           years.

3           The adjustment made each fiscal year under this  
4           paragraph shall be added on a compounded basis to  
5           the sum of all adjustments made each fiscal year  
6           after fiscal year 2013 under this paragraph.

7           “(2) WORKLOAD ADJUSTMENT.—For fiscal  
8           year 2014 and subsequent fiscal years, after the fee  
9           revenues established in subsection (b) are adjusted  
10          for a fiscal year for inflation in accordance with  
11          paragraph (1), the fee revenues shall be adjusted  
12          further for such fiscal year to reflect changes in the  
13          workload of the Secretary for the process for the re-  
14          view of human drug applications. With respect to  
15          such adjustment:

16          “(A) The adjustment shall be determined  
17          by the Secretary based on a weighted average  
18          of the change in the total number of human  
19          drug applications (adjusted for changes in re-  
20          view activities, as described in the notice that  
21          the Secretary is required to publish in the Fed-  
22          eral Register under this subparagraph), efficacy  
23          supplements, and manufacturing supplements  
24          submitted to the Secretary, and the change in  
25          the total number of active commercial investiga-

1            tional new drug applications (adjusted for  
2            changes in review activities, as so described)  
3            during the most recent 12-month period for  
4            which data on such submissions is available.  
5            The Secretary shall publish in the Federal Reg-  
6            ister the fee revenues and fees resulting from  
7            the adjustment and the supporting methodolo-  
8            gies.

9            “(B) Under no circumstances shall the ad-  
10          justment result in fee revenues for a fiscal year  
11          that are less than the sum of the amount under  
12          subsection (b)(1)(A) and the amount under  
13          subsection (b)(1)(B), as adjusted for inflation  
14          under paragraph (1).

15          “(C) The Secretary shall contract with an  
16          independent accounting or consulting firm to  
17          periodically review the adequacy of the adjust-  
18          ment and publish the results of those reviews.  
19          The first review shall be conducted and pub-  
20          lished by the end of fiscal year 2013 (to exam-  
21          ine the performance of the adjustment since fis-  
22          cal year 2009), and the second review shall be  
23          conducted and published by the end of fiscal  
24          year 2015 (to examine the continued perform-  
25          ance of the adjustment). The reports shall

1 evaluate whether the adjustment reasonably  
2 represents actual changes in workload volume  
3 and complexity and present options to dis-  
4 continue, retain, or modify any elements of the  
5 adjustment. The reports shall be published for  
6 public comment. After review of the reports and  
7 receipt of public comments, the Secretary shall,  
8 if warranted, adopt appropriate changes to the  
9 methodology. If the Secretary adopts changes to  
10 the methodology based on the first report, the  
11 changes shall be effective for the first fiscal  
12 year for which fees are set after the Secretary  
13 adopts such changes and each subsequent fiscal  
14 year.

15 “(3) FINAL YEAR ADJUSTMENT.—For fiscal  
16 year 2017, the Secretary may, in addition to adjust-  
17 ments under this paragraph and paragraphs (1) and  
18 (2), further increase the fee revenues and fees estab-  
19 lished in subsection (b) if such an adjustment is nec-  
20 essary to provide for not more than 3 months of op-  
21 erating reserves of carryover user fees for the proc-  
22 ess for the review of human drug applications for  
23 the first 3 months of fiscal year 2018. If such an  
24 adjustment is necessary, the rationale for the  
25 amount of the increase shall be contained in the an-



1 nual notice establishing fee revenues and fees for fis-  
2 cal year 2017. If the Secretary has carryover bal-  
3 ances for such process in excess of 3 months of such  
4 operating reserves, the adjustment under this sub-  
5 paragraph shall not be made.

6 “(4) ANNUAL FEE SETTING.—The Secretary  
7 shall, not later than 60 days before the start of each  
8 fiscal year that begins after September 30, 2012, es-  
9 tablish, for the next fiscal year, application, product,  
10 and establishment fees under subsection (a), based  
11 on the revenue amounts established under subsection  
12 (b) and the adjustments provided under this sub-  
13 section.

14 “(5) LIMIT.—The total amount of fees charged,  
15 as adjusted under this subsection, for a fiscal year  
16 may not exceed the total costs for such fiscal year  
17 for the resources allocated for the process for the re-  
18 view of human drug applications.”; and

19 (4) in subsection (g)—

20 (A) in paragraph (1), by striking “Fees  
21 authorized” and inserting “Subject to para-  
22 graph (2)(C), fees authorized”;

23 (B) in paragraph (2)—

1 (i) in subparagraph (A)(i), by striking  
2 “shall be retained” and inserting “shall be  
3 collected and available”;

4 (ii) in subparagraph (A)(ii), by strik-  
5 ing “shall only be collected and available”  
6 and inserting “shall be available”; and

7 (iii) by adding at the end the fol-  
8 lowing new subparagraph:

9 “(C) PROVISION FOR EARLY PAYMENTS.—  
10 Payment of fees authorized under this section  
11 for a fiscal year, prior to the due date for such  
12 fees, may be accepted by the Secretary in ac-  
13 cordance with authority provided in advance in  
14 a prior year appropriations Act.”;

15 (C) in paragraph (3), by striking “fiscal  
16 years 2008 through 2012” and inserting “fiscal  
17 years 2013 through 2017”; and

18 (D) in paragraph (4)—

19 (i) by striking “fiscal years 2008  
20 through 2010” and inserting “fiscal years  
21 2013 through 2015”;

22 (ii) by striking “fiscal year 2011” and  
23 inserting “fiscal year 2016”;

- 1 (iii) by striking “fiscal years 2008  
2 though 2011” and inserting “fiscal years  
3 2013 through 2016”; and  
4 (iv) by striking “fiscal year 2012”  
5 and inserting “fiscal year 2017”.

6 **SEC. 104. REAUTHORIZATION; REPORTING REQUIREMENTS.**

7 Section 736B (21 U.S.C. 379h–2) is amended—

8 (1) by amending subsection (a) to read as fol-  
9 lows:

10 “(a) PERFORMANCE REPORT.—

11 “(1) IN GENERAL.—Beginning with fiscal year  
12 2013, not later than 120 days after the end of each  
13 fiscal year for which fees are collected under this  
14 part, the Secretary shall prepare and submit to the  
15 Committee on Energy and Commerce of the House  
16 of Representatives and the Committee on Health,  
17 Education, Labor, and Pensions of the Senate a re-  
18 port concerning—

19 “(A) the progress of the Food and Drug  
20 Administration in achieving the goals identified  
21 in the letters described in section 101(b) of the  
22 Prescription Drug User Fee Amendments of  
23 2012 during such fiscal year and the future  
24 plans of the Food and Drug Administration for  
25 meeting the goals, including the status of the

1 independent assessment described in such let-  
2 ters; and

3 “(B) the progress of the Center for Drug  
4 Evaluation and Research and the Center for  
5 Biologics Evaluation and Research in achieving  
6 the goals, and future plans for meeting the  
7 goals, including, for each review division—

8 “(i) the number of original standard  
9 new drug applications and biologics license  
10 applications filed per fiscal year for each  
11 review division;

12 “(ii) the number of original priority  
13 new drug applications and biologics license  
14 applications filed per fiscal year for each  
15 review division;

16 “(iii) the number of standard efficacy  
17 supplements filed per fiscal year for each  
18 review division;

19 “(iv) the number of priority efficacy  
20 supplements filed per fiscal year for each  
21 review division;

22 “(v) the number of applications filed  
23 for review under accelerated approval per  
24 fiscal year for each review division;

1 “(vi) the number of applications filed  
 2 for review as fast track products per fiscal  
 3 year for each review division; and

4 “(vii) the number of applications filed  
 5 for orphan-designated products per fiscal  
 6 year for each review division.

7 “(2) INCLUSION.—The report under this sub-  
 8 section for a fiscal year shall include information on  
 9 all previous cohorts for which the Secretary has not  
 10 given a complete response on all human drug appli-  
 11 cations and supplements in the cohort.”.

12 (2) in subsection (b), by striking “2008” and  
 13 inserting “2013”; and

14 (3) in subsection (d), by striking “2012” each  
 15 place it appears and inserting “2017”.

16 **SEC. 105. SUNSET DATES.**

17 (a) AUTHORIZATION.—Sections 735 and 736 (21  
 18 U.S.C. 379g; 379h) are repealed October 1, 2017.

19 (b) REPORTING REQUIREMENTS.—Section 736B (21  
 20 U.S.C. 379h–2) is repealed January 31, 2018.

21 (c) PREVIOUS SUNSET PROVISION.—Section 106 of  
 22 the Prescription Drug User Fee Amendments of 2007  
 23 (Title I of Public Law 110–85) is repealed.

24 (d) TECHNICAL CLARIFICATIONS.—

1           (1) Effective September 30, 2007, section 508  
2           of the Prescription Drug User Fee Amendments Act  
3           of 2002 (Title V of Public Law 107–188) is re-  
4           pealed.

5           (2) Effective September 30, 2002, section 107  
6           of the Food and Drug Administration Modernization  
7           Act of 1997 (Public Law 105–115) is repealed.

8           (3) Effective September 30, 1997, section 105  
9           of the Prescription Drug User Fee Act of 1992  
10          (Public Law 102–571) is repealed.

11 **SEC. 106. EFFECTIVE DATE.**

12          The amendments made by this title shall take effect  
13 on October 1, 2012, or the date of the enactment of this  
14 Act, whichever is later, except that fees under part 2 of  
15 subchapter C of chapter VII of the Federal Food, Drug,  
16 and Cosmetic Act shall be assessed for all human drug  
17 applications received on or after October 1, 2012, regard-  
18 less of the date of the enactment of this Act.

19 **SEC. 107. SAVINGS CLAUSE.**

20          Notwithstanding the amendments made by this title,  
21 part 2 of subchapter C of chapter VII of the Federal Food,  
22 Drug, and Cosmetic Act, as in effect on the day before  
23 the date of the enactment of this title, shall continue to  
24 be in effect with respect to human drug applications and  
25 supplements (as defined in such part as of such day) that

1 on or after October 1, 2007, but before October 1, 2012,  
2 were accepted by the Food and Drug Administration for  
3 filing with respect to assessing and collecting any fee re-  
4 quired by such part for a fiscal year prior to fiscal year  
5 2012.

## 6 **TITLE II—MEDICAL DEVICE** 7 **USER FEE AMENDMENTS OF 2012**

### 8 **SEC. 201. SHORT TITLE; FINDINGS.**

9 (a) SHORT TITLE.—This Act may be cited as the  
10 “Medical Device User Fee Amendments of 2012”.

11 (b) FINDINGS.—The Congress finds that the fees au-  
12 thorized under the amendments made by this title will be  
13 dedicated toward expediting the process for the review of  
14 device applications and for assuring the safety and effec-  
15 tiveness of devices, as set forth in the goals identified for  
16 purposes of part 3 of subchapter C of chapter VII of the  
17 Federal Food, Drug, and Cosmetic Act in the letters from  
18 the Secretary of Health and Human Services to the Chair-  
19 man of the Committee on Health, Education, Labor, and  
20 Pensions of the Senate and the Chairman of the Com-  
21 mittee on Energy and Commerce of the House of Rep-  
22 resentatives, as set forth in the Congressional Record.

### 23 **SEC. 202. DEFINITIONS.**

24 Section 737 (21 U.S.C. 379i) is amended—

1 (1) in paragraph (9), by striking “incurred”  
 2 after “expenses”;

3 (2) in paragraph (10), by striking “October  
 4 2001” and inserting “October 2011”; and

5 (3) in paragraph (13), by striking “is required  
 6 to register” and all that follows through the end of  
 7 paragraph (13) and inserting the following: “is reg-  
 8 istered (or is required to register) with the Secretary  
 9 under section 510 because such establishment is en-  
 10 gaged in the manufacture, preparation, propagation,  
 11 compounding, or processing of a device.”.

12 **SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

13 (a) TYPES OF FEES.—Section 738(a) (21 U.S.C.  
 14 379j(a)) is amended—

15 (1) in paragraph (1), by striking “fiscal year  
 16 2008” and inserting “fiscal year 2013”;

17 (2) in paragraph (2)(A)—

18 (A) in the matter preceding clause (i)—

19 (i) by striking “subsections (d) and  
 20 (e)” and inserting “subsections (d), (e),  
 21 and (f)”;

22 (ii) by striking “October 1, 2002” and  
 23 inserting “October 1, 2012”; and

24 (iii) by striking “subsection (c)(1)”  
 25 and inserting “subsection (c)”;



1 (B) in clause (viii), by striking “1.84” and  
2 inserting “2”; and  
3 (3) in paragraph (3)—

4 (A) in subparagraph (A), by inserting  
5 “and subsection (f)” after “subparagraph (B)”;  
6 and

7 (B) in subparagraph (C), by striking “ini-  
8 tial registration” and all that follows through  
9 “section 510.” and inserting “later of—

10 “(i) the initial or annual registration  
11 (as applicable) of the establishment under  
12 section 510; or

13 “(ii) the first business day after the  
14 date of enactment of an appropriations Act  
15 providing for the collection and obligation  
16 of fees for such year under this section.”.

17 (b) FEE AMOUNTS.—Section 738(b) (21 U.S.C.  
18 379j(b)) is amended to read as follows:

19 “(b) FEE AMOUNTS.—

20 “(1) IN GENERAL.—Subject to subsections (c),  
21 (d), (e), (f), and (i), for each of fiscal years 2013  
22 through 2017, fees under subsection (a) shall be de-  
23 rived from the base fee amounts specified in para-  
24 graph (2), to generate the total revenue amounts  
25 specified in paragraph (3).

1           “(2) BASE FEE AMOUNTS SPECIFIED.—For  
 2           purposes of paragraph (1), the base fee amounts  
 3           specified in this paragraph are as follows:

“Fee Type	Fiscal Year 2013	Fiscal Year 2014	Fiscal Year 2015	Fiscal Year 2016	Fiscal Year 2017
Premarket Application .....	\$248,000	\$252,960	\$258,019	\$263,180	\$268,443
Establishment Registration .....	\$2,575	\$3,200	\$3,750	\$3,872	\$3,872

4           “(3) TOTAL REVENUE AMOUNTS.—For pur-  
 5           poses of paragraph (1), the total revenue amounts  
 6           specified in this paragraph are as follows:

7                   “(A) \$97,722,301 for fiscal year 2013.

8                   “(B) \$112,580,497 for fiscal year 2014.

9                   “(C) \$125,767,107 for fiscal year 2015.

10                  “(D) \$129,339,949 for fiscal year 2016.

11                  “(E) \$130,184,348 for fiscal year 2017.”.

12           (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section  
 13 738(c) (21 U.S.C. 379j(c)) is amended—

14                   (1) in the subsection heading, by inserting “;  
 15           ADJUSTMENTS” after “SETTING”;

16                   (2) by striking paragraphs (1) and (2);

17                   (3) by redesignating paragraphs (3) and (4) as  
 18           paragraphs (4) and (5), respectively; and

19                   (4) by inserting before paragraph (4), as so re-  
 20           designated, the following:

21                   “(1) IN GENERAL.—The Secretary shall, 60  
 22           days before the start of each fiscal year after Sep-  
 23           tember 30, 2012, establish fees under subsection (a),

1 based on amounts specified under subsection (b) and  
2 the adjustments provided under this subsection, and  
3 publish such fees, and the rationale for any adjust-  
4 ments to such fees, in the Federal Register.

5 “(2) INFLATION ADJUSTMENTS.—

6 “(A) ADJUSTMENT TO TOTAL REVENUE  
7 AMOUNTS.—For fiscal year 2014 and each sub-  
8 sequent fiscal year, the Secretary shall adjust  
9 the total revenue amount specified in subsection  
10 (b)(3) for such fiscal year by multiplying such  
11 amount by the applicable inflation adjustment  
12 under subparagraph (B) for such year.

13 “(B) APPLICABLE INFLATION ADJUST-  
14 MENT TO TOTAL REVENUE AMOUNTS.—The ap-  
15 plicable inflation adjustment for a fiscal year  
16 is—

17 “(i) for fiscal year 2014, the base in-  
18 flation adjustment under subparagraph (C)  
19 for such fiscal year; and

20 “(ii) for fiscal year 2015 and each  
21 subsequent fiscal year, the product of—

22 “(I) the base inflation adjust-  
23 ment under subparagraph (C) for  
24 such fiscal year; and

1 “(II) the product of the base in-  
2 flation adjustment under subpara-  
3 graph (C) for each of the fiscal years  
4 preceding such fiscal year, beginning  
5 with fiscal year 2014.

6 “(C) BASE INFLATION ADJUSTMENT TO  
7 TOTAL REVENUE AMOUNTS.—

8 “(i) IN GENERAL.—Subject to further  
9 adjustment under clause (ii), the base in-  
10 flation adjustment for a fiscal year is the  
11 sum of one plus—

12 “(I) the average annual percent  
13 change in the cost, per full-time equiv-  
14 alent position of the Food and Drug  
15 Administration, of all personnel com-  
16 pensation and benefits paid with re-  
17 spect to such positions for the first 3  
18 years of the preceding 4 fiscal years,  
19 multiplied by 0.60; and

20 “(II) the average annual percent  
21 change that occurred in the Consumer  
22 Price Index for urban consumers  
23 (Washington-Baltimore, DC–MD–VA–  
24 WV; Not Seasonally Adjusted; All  
25 items; Annual Index) for the first 3

1 years of the preceding 4 years of  
2 available data multiplied by 0.40.

3 “(ii) LIMITATIONS.—For purposes of  
4 subparagraph (B), if the base inflation ad-  
5 justment for a fiscal year under clause  
6 (i)—

7 “(I) is less than 1, such adjust-  
8 ment shall be considered to be equal  
9 to 1; or

10 “(II) is greater than 1.04, such  
11 adjustment shall be considered to be  
12 equal to 1.04.

13 “(D) ADJUSTMENT TO BASE FEE  
14 AMOUNTS.—For each of fiscal years 2014  
15 through 2017, the base fee amounts specified in  
16 subsection (b)(2) shall be adjusted as needed,  
17 on a uniform proportionate basis, to generate  
18 the total revenue amounts under subsection  
19 (b)(3), as adjusted for inflation under subpara-  
20 graph (A).

21 “(3) VOLUME-BASED ADJUSTMENTS TO ESTAB-  
22 LISHMENT REGISTRATION BASE FEES.—For each of  
23 fiscal years 2014 through 2017, after the base fee  
24 amounts specified in subsection (b)(2) are adjusted  
25 under paragraph (2)(D), the base establishment reg-

1       istration fee amounts specified in such subsection  
 2       shall be further adjusted, as the Secretary estimates  
 3       is necessary in order for total fee collections for such  
 4       fiscal year to generate the total revenue amounts, as  
 5       adjusted under paragraph (2).”.

6       (d) FEE WAIVER OR REDUCTION.—Section 738 (21  
 7 U.S.C. 379j) is amended by—

8           (1) redesignating subsections (f) through (k) as  
 9       subsections (g) through (l), respectively; and

10          (2) by inserting after subsection (e) the fol-  
 11       lowing new subsection (f):

12       “(f) FEE WAIVER OR REDUCTION.—

13           “(1) IN GENERAL.—The Secretary may, at the  
 14       Secretary’s sole discretion, grant a waiver or reduc-  
 15       tion of fees under subsection (a)(2) or (a)(3) if the  
 16       Secretary finds that such waiver or reduction is in  
 17       the interest of public health.

18           “(2) LIMITATION.—The sum of all fee waivers  
 19       or reductions granted by the Secretary in any fiscal  
 20       year under paragraph (1) shall not exceed 2 percent  
 21       of the total fee revenue amounts established for such  
 22       year under subsection (c).

23           “(3) DURATION.—The authority provided by  
 24       this subsection terminates October 1, 2017.”.

1 (e) CONDITIONS.—Section 738(h)(1)(A) (21 U.S.C.  
2 379j(h)(1)(A)), as redesignated by subsection (d)(1), is  
3 amended by striking “\$205,720,000” and inserting  
4 “\$280,587,000”.

5 (f) CREDITING AND AVAILABILITY OF FEES.—Sec-  
6 tion 738(i) (21 U.S.C. 379j(i)), as redesignated by sub-  
7 section (d)(1), is amended—

8 (1) in paragraph (1), by striking “Fees author-  
9 ized” and inserting “Subject to paragraph (2)(C),  
10 fees authorized”;

11 (2) in paragraph (2)—

12 (A) in subparagraph (A)—

13 (i) in clause (i), by striking “shall be  
14 retained” and inserting “subject to sub-  
15 paragraph (C), shall be collected and avail-  
16 able”; and

17 (ii) in clause (ii)—

18 (I) by striking “collected and”  
19 after “shall only be”; and

20 (II) by striking “fiscal year  
21 2002” and inserting “fiscal year  
22 2009”; and

23 (B) by adding at the end, the following:

24 “(C) PROVISION FOR EARLY YEAR PAY-  
25 MENTS.—Payment of fees authorized under this

1 section for a fiscal year, prior to the due date  
2 for such fees, may be accepted by the Secretary  
3 in accordance with authority provided in ad-  
4 vance in a prior year appropriations Act.”;

5 (3) in paragraph (3), by amending to read as  
6 follows:

7 “(3) AUTHORIZATIONS OF APPROPRIATIONS.—  
8 For each of the fiscal years 2013 through 2017,  
9 there is authorized to be appropriated for fees under  
10 this section an amount equal to the total revenue  
11 amount specified under subsection (b)(3) for the fis-  
12 cal year, as adjusted under subsection (c) and, for  
13 fiscal year 2017 only, as further adjusted under  
14 paragraph (4).”; and

15 (4) in paragraph (4)—

16 (A) by striking “fiscal years 2008, 2009,  
17 and 2010” and inserting “fiscal years 2013,  
18 2014, and 2015”;

19 (B) by striking “fiscal year 2011” and in-  
20 serting “fiscal year 2016”;

21 (C) by striking “June 30, 2011” and in-  
22 serting “June 30, 2016”;

23 (D) by striking “the amount of fees speci-  
24 fied in aggregate in” and inserting “the cumu-  
25 lative amount appropriated pursuant to”;



1 (E) by striking “aggregate amount in” be-  
 2 fore “excess shall be credited”; and

3 (F) by striking “fiscal year 2012” and in-  
 4 serting “fiscal year 2017”.

5 (g) CONFORMING AMENDMENT.—Section  
 6 515(c)(4)(A) (21 U.S.C. 360e(c)(4)(A)) is amended by  
 7 striking “738(g)” and inserting “738(h)”.

8 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.**

9 (a) REAUTHORIZATION.—Section 738A(b) (21  
 10 U.S.C. 379j–1(b)) is amended—

11 (1) in paragraph (1), by striking “2012” and  
 12 inserting “2017”; and

13 (2) in paragraph (5), by striking “2012” and  
 14 inserting “2017”.

15 (b) PERFORMANCE REPORTS.—Section 738A(a) (21  
 16 U.S.C. 379j–1(a)) is amended—

17 (1) by striking paragraph (1) and inserting the  
 18 following:

19 “(1) PERFORMANCE REPORT.—

20 “(A) IN GENERAL.—Beginning with fiscal  
 21 year 2013, for each fiscal year for which fees  
 22 are collected under this part, the Secretary  
 23 shall prepare and submit to the Committee on  
 24 Health, Education, Labor, and Pensions of the  
 25 Senate and the Committee on Energy and Com-

merce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 201(b) of the Medical Device User Fee Amendments of 2012 during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

“(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to the letters described in section 201(b) of the Medical Device User Fee Amendments Act of 2012, the Secretary shall make such information publicly available on the Internet Website of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies. This information shall include the status of the independent assessment identified in the letters described in such section 201(b).

“(C) UPDATES.—The Secretary shall include in each report under subparagraph (A)

1 information on all previous cohorts for which  
2 the Secretary has not given a complete response  
3 on all device premarket applications and re-  
4 ports, supplements, and premarket notifications  
5 in the cohort.”; and

6 (2) in paragraph (2), by striking “2008  
7 through 2012” and inserting “2013 through 2017”.

8 **SEC. 205. SAVINGS CLAUSE.**

9 Notwithstanding the amendments made by this title,  
10 part 3 of subchapter C of chapter VII of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in  
12 effect on the day before the date of the enactment of this  
13 title, shall continue to be in effect with respect to the sub-  
14 missions listed in section 738(a)(2)(A) of such Act (as de-  
15 fined in such part as of such day) that on or after October  
16 1, 2007, but before October 1, 2012, were accepted by  
17 the Food and Drug Administration for filing with respect  
18 to assessing and collecting any fee required by such part  
19 for a fiscal year prior to fiscal year 2013.

20 **SEC. 206. EFFECTIVE DATE.**

21 The amendments made by this title shall take effect  
22 on October 1, 2012, or the date of the enactment of this  
23 Act, whichever is later, except that fees under part 3 of  
24 subchapter C of chapter VII of the Federal Food, Drug,  
25 and Cosmetic Act shall be assessed for all submissions list-

1 ed in section 738(a)(2)(A) of such Act received on or after  
 2 October 1, 2012, regardless of the date of the enactment  
 3 of this Act.

4 **SEC. 207. SUNSET CLAUSE.**

5 (a) IN GENERAL.—Sections 737 and 738 of the Fed-  
 6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 739i; 739j)  
 7 shall cease to be effective October 1, 2017. Section 738A  
 8 (21 U.S.C. 739j–1) of the Federal Food, Drug, and Cos-  
 9 metic Act (regarding reauthorization and reporting re-  
 10 quirements) are repealed January 31, 2018.

11 (b) PREVIOUS SUNSET PROVISION.—Section 217 of  
 12 the Medical Device User Fee Amendments of 2007 (Title  
 13 II of Public Law 110–85) is repealed.

14 (c) TECHNICAL CLARIFICATION.—Effective Sep-  
 15 tember 30, 2007, section 107 of the Medical Device User  
 16 Fee and Modernization Act of 2002 (Public Law 107–  
 17 250) is repealed.

18 **SEC. 208. STREAMLINED HIRING AUTHORITY TO SUPPORT**  
 19 **ACTIVITIES RELATED TO THE PROCESS FOR**  
 20 **THE REVIEW OF DEVICE APPLICATIONS.**

21 Subchapter A of chapter VII (21 U.S.C. 371 et seq.)  
 22 is amended by inserting after section 713 the following  
 23 new section:

1   **“SEC. 714. STREAMLINED HIRING AUTHORITY.**

2           “(a) IN GENERAL.—In addition to any other per-  
3   sonnel authorities under other provisions of law, the Sec-  
4   retary may, without regard to the provisions of title 5,  
5   United States Code, governing appointments in the com-  
6   petitive service, appoint employees to positions in the Food  
7   and Drug Administration to perform, administer, or sup-  
8   port activities described in subsection (b), if the Secretary  
9   determines that such appointments are needed to achieve  
10  the objectives specified in subsection (c).

11          “(b) ACTIVITIES DESCRIBED.—The activities de-  
12  scribed in this subsection are activities under this Act re-  
13  lated to the process for the review of device applications  
14  (as defined in section 737(8)).

15          “(c) OBJECTIVES SPECIFIED.—The objectives speci-  
16  fied in this subsection are with respect to the activities  
17  under subsection (b)(1), the goals referred to in section  
18  738A(a)(1).

19          “(d) INTERNAL CONTROLS.—The Secretary shall in-  
20  stitute appropriate internal controls for appointments  
21  under this section.

22          “(e) SUNSET.—The authority to appoint employees  
23  under this section shall terminate on the date that is three  
24  years after the date of enactment of this section.”.

1     **TITLE III—FEES RELATING TO**  
 2                     **GENERIC DRUGS**

3     **SEC. 301. SHORT TITLE.**

4             (a) **SHORT TITLE.**—This title may be cited as the  
 5     “Generic Drug User Fee Amendments of 2012”.

6             (b) **FINDING.**—The Congress finds that the fees au-  
 7     thorized by the amendments made in this title will be dedi-  
 8     cated to human generic drug activities, as set forth in the  
 9     goals identified for purposes of part 7 of subchapter C  
 10    of chapter VII of the Federal Food, Drug, and Cosmetic  
 11    Act, in the letters from the Secretary of Health and  
 12    Human Services to the Chairman of the Committee on  
 13    Health, Education, Labor, and Pensions of the Senate and  
 14    the Chairman of the Committee on Energy and Commerce  
 15    of the House of Representatives, as set forth in the Con-  
 16    gressional Record.

17    **SEC. 302. AUTHORITY TO ASSESS AND USE HUMAN GE-**  
 18                     **NERIC DRUG FEES.**

19             Subchapter C of chapter VII (21 U.S.C. 379f et seq.)  
 20    is amended by adding at the end the following:

21     **“PART 7—FEES RELATING TO GENERIC DRUGS**

22     **“SEC. 744A. DEFINITIONS.**

23             “For purposes of this part:

24                     “(1) The term ‘abbreviated new drug applica-  
 25     tion’—

1           “(A) means an application submitted  
2           under section 505(j), an abbreviated application  
3           submitted under section 507 (as in effect on the  
4           day before the date of enactment of the Food  
5           and Drug Administration Modernization Act of  
6           1997), or an abbreviated new drug application  
7           submitted pursuant to regulations in effect  
8           prior to the implementation of the Drug Price  
9           Competition and Patent Term Restoration Act  
10          of 1984; and

11          “(B) does not include an application for a  
12          positron emission tomography drug.

13          “(2) The term ‘active pharmaceutical ingre-  
14          dient’ means—

15               “(A) a substance, or a mixture when the  
16               substance is unstable or cannot be transported  
17               on its own, intended—

18                       “(i) to be used as a component of a  
19                       drug; and

20                       “(ii) to furnish pharmacological activ-  
21                       ity or other direct effect in the diagnosis,  
22                       cure, mitigation, treatment, or prevention  
23                       of disease, or to affect the structure or any  
24                       function of the human body; or

1           “(B) a substance intended for final crys-  
2           tallization, purification, or salt formation, or  
3           any combination of those activities, to become a  
4           substance or mixture described in subparagraph  
5           (A).

6           “(3) The term ‘adjustment factor’ means a fac-  
7           tor applicable to a fiscal year that is the Consumer  
8           Price Index for all urban consumers (all items;  
9           United States city average) for October of the pre-  
10          ceding fiscal year divided by such Index for October  
11          2011.

12          “(4) The term ‘affiliate’ means a business enti-  
13          ty that has a relationship with a second business en-  
14          tity if, directly or indirectly—

15               “(A) one business entity controls, or has  
16               the power to control, the other business entity;  
17               or

18               “(B) a third party controls, or has power  
19               to control, both of the business entities.

20          “(5)(A) The term ‘facility’—

21               “(i) means a business or other entity—

22                       “(I) under one management, either di-  
23                       rect or indirect; and

24                       “(II) at one geographic location or ad-  
25                       dress engaged in manufacturing or proc-



1           essing an active pharmaceutical ingredient  
2           or a finished dosage form; and

3           “(ii) does not include a business or other  
4           entity whose only manufacturing or processing  
5           activities are one or more of the following: re-  
6           packaging, relabeling, or testing.

7           “(B) For purposes of subparagraph (A), sepa-  
8           rate buildings within close proximity are considered  
9           to be at one geographic location or address if the ac-  
10          tivities in them are—

11           “(i) closely related to the same business  
12          enterprise;

13           “(ii) under the supervision of the same  
14          local management; and

15           “(iii) capable of being inspected by the  
16          Food and Drug Administration during a single  
17          inspection.

18          “(C) If a business or other entity would meet  
19          the definition of a facility under this paragraph but  
20          for being under multiple management, the business  
21          or other entity is deemed to constitute multiple fa-  
22          cilities, one per management entity, for purposes of  
23          this paragraph.

24          “(6) The term ‘finished dosage form’ means—

1           “(A) a drug product in the form in which  
2           it will be administered to a patient, such as a  
3           tablet, capsule, solution, or topical application;

4           “(B) a drug product in a form in which re-  
5           constitution is necessary prior to administration  
6           to a patient, such as oral suspensions or  
7           lyophilized powders; or

8           “(C) any combination of an active pharma-  
9           ceutical ingredient with another component of a  
10          drug product for purposes of production of a  
11          drug product described in subparagraph (A) or  
12          (B).

13          “(7) The term ‘generic drug submission’ means  
14          an abbreviated new drug application, an amendment  
15          to an abbreviated new drug application, or a prior  
16          approval supplement to an abbreviated new drug ap-  
17          plication.

18          “(8) The term ‘human generic drug activities’  
19          means the following activities of the Secretary asso-  
20          ciated with generic drugs and inspection of facilities  
21          associated with generic drugs:

22                 “(A) The activities necessary for the re-  
23                 view of generic drug submissions, including re-  
24                 view of drug master files referenced in such  
25                 submissions.

1 “(B) The issuance of—

2 “(i) approval letters which approve  
3 abbreviated new drug applications or sup-  
4 plements to such applications; or

5 “(ii) complete response letters which  
6 set forth in detail the specific deficiencies  
7 in such applications and, where appro-  
8 priate, the actions necessary to place such  
9 applications in condition for approval.

10 “(C) The issuance of letters related to  
11 Type II active pharmaceutical drug master files  
12 which—

13 “(i) set forth in detail the specific de-  
14 ficiencies in such submissions, and where  
15 appropriate, the actions necessary to re-  
16 solve those deficiencies; or

17 “(ii) document that no deficiencies  
18 need to be addressed.

19 “(D) Inspections related to generic drugs.

20 “(E) Monitoring of research conducted in  
21 connection with the review of generic drug sub-  
22 missions and drug master files.

23 “(F) Postmarket safety activities with re-  
24 spect to drugs approved under abbreviated new

1 drug applications or supplements, including the  
2 following activities:

3 “(i) Collecting, developing, and re-  
4 viewing safety information on approved  
5 drugs, including adverse event reports.

6 “(ii) Developing and using improved  
7 adverse-event data-collection systems, in-  
8 cluding information technology systems.

9 “(iii) Developing and using improved  
10 analytical tools to assess potential safety  
11 problems, including access to external data  
12 bases.

13 “(iv) Implementing and enforcing sec-  
14 tion 505(o) (relating to postapproval stud-  
15 ies and clinical trials and labeling changes)  
16 and section 505(p) (relating to risk evalua-  
17 tion and mitigation strategies) insofar as  
18 those activities relate to abbreviated new  
19 drug applications.

20 “(v) Carrying out section 505(k)(5)  
21 (relating to adverse-event reports and  
22 postmarket safety activities).

23 “(G) Regulatory science activities related  
24 to generic drugs.

1           “(9) The term ‘positron emission tomography  
2       drug’ has the meaning given to the term ‘com-  
3       pounded positron emission tomography drug’ in sec-  
4       tion 201(ii), except that paragraph (1)(B) of such  
5       section shall not apply.

6           “(10) The term ‘prior approval supplement’  
7       means a request to the Secretary to approve a  
8       change in the drug substance, drug product, produc-  
9       tion process, quality controls, equipment, or facilities  
10      covered by an approved abbreviated new drug appli-  
11      cation when that change has a substantial potential  
12      to have an adverse effect on the identity, strength,  
13      quality, purity, or potency of the drug product as  
14      these factors may relate to the safety or effective-  
15      ness of the drug product.

16          “(11) The term ‘resources allocated for human  
17      generic drug activities’ means the expenses for—

18               “(A) officers and employees of the Food  
19              and Drug Administration, contractors of the  
20              Food and Drug Administration, advisory com-  
21              mittees, and costs related to such officers and  
22              employees and to contracts with such contrac-  
23              tors;

1           “(B) management of information, and the  
2           acquisition, maintenance, and repair of com-  
3           puter resources;

4           “(C) leasing, maintenance, renovation, and  
5           repair of facilities and acquisition, maintenance,  
6           and repair of fixtures, furniture, scientific  
7           equipment, and other necessary materials and  
8           supplies; and

9           “(D) collecting fees under subsection (a)  
10          and accounting for resources allocated for the  
11          review of abbreviated new drug applications and  
12          supplements and inspection related to generic  
13          drugs.

14          “(12) The term ‘Type II active pharmaceutical  
15          ingredient drug master file’ means a submission of  
16          information to the Secretary by a person that in-  
17          tends to authorize the Food and Drug Administra-  
18          tion to reference the information to support approval  
19          of a generic drug submission without the submitter  
20          having to disclose the information to the generic  
21          drug submission applicant.

1 **“SEC. 744B. AUTHORITY TO ASSESS AND USE HUMAN GE-**  
2 **NERIC DRUG FEES.**

3 “(a) TYPES OF FEES.—Beginning in fiscal year  
4 2013, the Secretary shall assess and collect fees in accord-  
5 ance with this section as follows:

6 “(1) ONE-TIME BACKLOG FEE FOR ABBRE-  
7 VIATED NEW DRUG APPLICATIONS PENDING ON OC-  
8 TOBER 1, 2012.—

9 “(A) IN GENERAL.—Each person that  
10 owns an abbreviated new drug application that  
11 is pending on October 1, 2012, and that has  
12 not received a tentative approval prior to that  
13 date, shall be subject to a fee for each such ap-  
14 plication, as calculated under subparagraph  
15 (B).

16 “(B) METHOD OF FEE AMOUNT CALCULA-  
17 TION.—The amount of each one-time backlog  
18 fee shall be calculated by dividing \$50,000,000  
19 by the total number of abbreviated new drug  
20 applications pending on October 1, 2012, that  
21 have not received a tentative approval as of that  
22 date.

23 “(C) NOTICE.—Not later than October 31,  
24 2012, the Secretary shall cause to be published  
25 in the Federal Register a notice announcing the

1 amount of the fee required by subparagraph  
2 (A).

3 “(D) FEE DUE DATE.—The fee required  
4 by subparagraph (A) shall be due no later than  
5 30 calendar days after the date of the publica-  
6 tion of the notice specified in subparagraph (C).

7 “(2) DRUG MASTER FILE FEE.—

8 “(A) IN GENERAL.—Each person that  
9 owns a Type II active pharmaceutical ingre-  
10 dient drug master file that is referenced on or  
11 after October 1, 2012, in a generic drug sub-  
12 mission by any initial letter of authorization  
13 shall be subject to a drug master file fee.

14 “(B) ONE-TIME PAYMENT.—If a person  
15 has paid a drug master file fee for a Type II  
16 active pharmaceutical ingredient drug master  
17 file, the person shall not be required to pay a  
18 subsequent drug master file fee when that Type  
19 II active pharmaceutical ingredient drug master  
20 file is subsequently referenced in generic drug  
21 submissions.

22 “(C) NOTICE.—

23 “(i) FISCAL YEAR 2013.—Not later  
24 than October 31, 2012, the Secretary shall  
25 cause to be published in the Federal Reg-



1           ister a notice announcing the amount of  
2           the drug master file fee for fiscal year  
3           2013.

4           “(ii) FISCAL YEAR 2014 THROUGH  
5           2017.—Not later than 60 days before the  
6           start of each of fiscal years 2014 through  
7           2017, the Secretary shall cause to be pub-  
8           lished in the Federal Register the amount  
9           of the drug master file fee established by  
10          this paragraph for such fiscal year.

11          “(D) AVAILABILITY FOR REFERENCE.—

12           “(i) IN GENERAL.—Subject to sub-  
13           section (g)(2)(C), for a generic drug sub-  
14           mission to reference a Type II active phar-  
15           maceutical ingredient drug master file, the  
16           drug master file must be deemed available  
17           for reference by the Secretary.

18           “(ii) CONDITIONS.—A drug master  
19           file shall be deemed available for reference  
20           by the Secretary if—

21           “(I) the person that owns a Type  
22           II active pharmaceutical ingredient  
23           drug master file has paid the fee re-  
24           quired under subparagraph (A) within  
25           20 calendar days after the applicable

1 due date under subparagraph (E);  
2 and

3 “(II) the drug master file has not  
4 failed an initial completeness assess-  
5 ment by the Secretary, in accordance  
6 with criteria to be published by the  
7 Secretary.

8 “(iii) LIST.—The Secretary shall  
9 make publicly available on the Internet  
10 Web site of the Food and Drug Adminis-  
11 tration a list of the drug master file num-  
12 bers that correspond to drug master files  
13 that have successfully undergone an initial  
14 completeness assessment, in accordance  
15 with criteria to be published by the Sec-  
16 retary, and are available for reference.

17 “(E) FEE DUE DATE.—

18 “(i) IN GENERAL.—Subject to clause  
19 (ii), a drug master file fee shall be due no  
20 later than the date on which the first ge-  
21 neric drug submission is submitted that  
22 references the associated Type II active  
23 pharmaceutical ingredient drug master file.

1 “(ii) LIMITATION.—No fee shall be  
2 due under subparagraph (A) for a fiscal  
3 year until the later of—

4 “(I) 30 calendar days after publi-  
5 cation of the notice provided for in  
6 clause (i) or (ii) of subparagraph (C),  
7 as applicable; or

8 “(II) 30 calendar days after the  
9 date of enactment of an appropria-  
10 tions Act providing for the collection  
11 and obligation of fees under this sec-  
12 tion.

13 “(3) ABBREVIATED NEW DRUG APPLICATION  
14 AND PRIOR APPROVAL SUPPLEMENT FILING FEE.—

15 “(A) IN GENERAL.—Each applicant that  
16 submits, on or after October 1, 2012, an abbrevi-  
17 ated new drug application or a prior approval  
18 supplement to an abbreviated new drug applica-  
19 tion shall be subject to a fee for each such sub-  
20 mission in the amount established under sub-  
21 section (d).

22 “(B) NOTICE.—

23 “(i) FISCAL YEAR 2013.—Not later  
24 than October 31, 2012, the Secretary shall  
25 cause to be published in the Federal Reg-

1           ister a notice announcing the amount of  
2           the fees under subparagraph (A) for fiscal  
3           year 2013.

4           “(ii) FISCAL YEARS 2014 THROUGH  
5           2017.—Not later than 60 days before the  
6           start of each of fiscal years 2014 through  
7           2017, the Secretary shall cause to be pub-  
8           lished in the Federal Register the amount  
9           of the fees under subparagraph (A) for  
10          such fiscal year.

11          “(C) FEE DUE DATE.—

12          “(i) IN GENERAL.—Except as pro-  
13          vided in clause (ii), the fees required by  
14          subparagraphs (A) and (F) shall be due no  
15          later than the date of submission of the  
16          abbreviated new drug application or prior  
17          approval supplement for which such fee ap-  
18          plies.

19          “(ii) SPECIAL RULE FOR 2013.—For  
20          fiscal year 2013, such fees shall be due on  
21          the later of—

22                  “(I) the date on which the fee is  
23                  due under clause (i);

1                   “(II) 30 calendar days after pub-  
2                   lication of the notice referred to in  
3                   subparagraph (B)(i); or

4                   “(III) if an appropriations Act is  
5                   not enacted providing for the collec-  
6                   tion and obligation of fees under this  
7                   section by the date of submission of  
8                   the application or prior approval sup-  
9                   plement for which the fees under sub-  
10                  paragraphs (A) and (F) apply, 30 cal-  
11                  endar days after the date that such an  
12                  appropriations Act is enacted.

13               “(D) REFUND OF FEE IF ABBREVIATED  
14               NEW DRUG APPLICATION IS NOT CONSIDERED  
15               TO HAVE BEEN RECEIVED.—The Secretary  
16               shall refund 75 percent of the fee paid under  
17               subparagraph (A) for any abbreviated new drug  
18               application or prior approval supplement to an  
19               abbreviated new drug application that the Sec-  
20               retary considers not to have been received with-  
21               in the meaning of section 505(j)(5)(A) for a  
22               cause other than failure to pay fees.

23               “(E) FEE FOR AN APPLICATION THE SEC-  
24               RETARY CONSIDERS NOT TO HAVE BEEN RE-  
25               CEIVED, OR THAT HAS BEEN WITHDRAWN.—An

1 abbreviated new drug application or prior ap-  
2 proval supplement that was submitted on or  
3 after October 1, 2012, and that the Secretary  
4 considers not to have been received, or that has  
5 been withdrawn, shall, upon resubmission of the  
6 application or a subsequent new submission fol-  
7 lowing the applicant's withdrawal of the appli-  
8 cation, be subject to a full fee under subpara-  
9 graph (A).

10 “(F) ADDITIONAL FEE FOR ACTIVE PHAR-  
11 MACEUTICAL INGREDIENT INFORMATION NOT  
12 INCLUDED BY REFERENCE TO TYPE II ACTIVE  
13 PHARMACEUTICAL INGREDIENT DRUG MASTER  
14 FILE.—An applicant that submits a generic  
15 drug submission on or after October 1, 2012,  
16 shall pay a fee, in the amount determined under  
17 subsection (d)(3), in addition to the fee re-  
18 quired under subparagraph (A), if—

19 “(i) such submission contains infor-  
20 mation concerning the manufacture of an  
21 active pharmaceutical ingredient at a facil-  
22 ity by means other than reference by a let-  
23 ter of authorization to a Type II active  
24 pharmaceutical drug master file; and

1                   “(ii) a fee in the amount equal to the  
2                   drug master file fee established in para-  
3                   graph (2) has not been previously paid  
4                   with respect to such information.

5                   “(4) GENERIC DRUG FACILITY FEE AND ACTIVE  
6                   PHARMACEUTICAL INGREDIENT FACILITY FEE.—

7                   “(A) IN GENERAL.—Facilities identified,  
8                   or intended to be identified, in at least one ge-  
9                   neric drug submission that is pending or ap-  
10                  proved to produce a finished dosage form of a  
11                  human generic drug or an active pharma-  
12                  ceutical ingredient contained in a human ge-  
13                  neric drug shall be subject to fees as follows:

14                 “(i) GENERIC DRUG FACILITY.—Each  
15                 person that owns a facility which is identi-  
16                 fied or intended to be identified in at least  
17                 one generic drug submission that is pend-  
18                 ing or approved to produce one or more  
19                 finished dosage forms of a human generic  
20                 drug shall be assessed an annual fee for  
21                 each such facility.

22                 “(ii) ACTIVE PHARMACEUTICAL IN-  
23                 GREDIENT FACILITY.—Each person that  
24                 owns a facility which produces, or which is  
25                 pending review to produce, one or more ac-

1           tive pharmaceutical ingredients identified,  
2           or intended to be identified, in at least one  
3           generic drug submission that is pending or  
4           approved or in a Type II active pharma-  
5           ceutical ingredient drug master file ref-  
6           erenced in such a generic drug submission,  
7           shall be assessed an annual fee for each  
8           such facility.

9           “(iii) FACILITIES PRODUCING BOTH  
10          ACTIVE PHARMACEUTICAL INGREDIENTS  
11          AND FINISHED DOSAGE FORMS.—Each  
12          person that owns a facility identified, or  
13          intended to be identified, in at least one  
14          generic drug submission that is pending or  
15          approved to produce both one or more fin-  
16          ished dosage forms subject to clause (i)  
17          and one or more active pharmaceutical in-  
18          gredients subject to clause (ii) shall be  
19          subject to fees under both such clauses for  
20          that facility.

21          “(B) AMOUNT.—The amount of fees estab-  
22          lished under subparagraph (A) shall be estab-  
23          lished under subsection (d).

24          “(C) NOTICE.—



1 “(i) FISCAL YEAR 2013.—For fiscal  
2 year 2013, the Secretary shall cause to be  
3 published in the Federal Register a notice  
4 announcing the amount of the fees pro-  
5 vided for in subparagraph (A) within the  
6 timeframe specified in subsection  
7 (d)(1)(B).

8 “(ii) FISCAL YEARS 2014 THROUGH  
9 2017.—Within the timeframe specified in  
10 subsection (d)(2), the Secretary shall cause  
11 to be published in the Federal Register the  
12 amount of the fees under subparagraph  
13 (A) for such fiscal year.

14 “(D) FEE DUE DATE.—

15 “(i) FISCAL YEAR 2013.—For fiscal  
16 year 2013, the fees under subparagraph  
17 (A) shall be due on the later of—

18 “(I) not later than 45 days after  
19 the publication of the notice under  
20 subparagraph (B); or

21 “(II) if an appropriations Act is  
22 not enacted providing for the collec-  
23 tion and obligation of fees under this  
24 section by the date of the publication  
25 of such notice, 30 days after the date

1                   that such an appropriations Act is en-  
2                   acted.

3                   “(ii) FISCAL YEARS 2014 THROUGH  
4                   2017.—For each of fiscal years 2014  
5                   through 2017, the fees under subpara-  
6                   graph (A) for such fiscal year shall be due  
7                   on the later of—

8                   “(I) the first business day on or  
9                   after October 1 of each such year; or

10                  “(II) the first business day after  
11                  the enactment of an appropriations  
12                  Act providing for the collection and  
13                  obligation of fees under this section  
14                  for such year.

15                  “(5) DATE OF SUBMISSION.—For purposes of  
16                  this part, a generic drug submission or Type II  
17                  pharmaceutical master file is deemed to be ‘sub-  
18                  mitted’ to the Food and Drug Administration—

19                  “(A) if it is submitted via a Food and  
20                  Drug Administration electronic gateway, on the  
21                  day when transmission to that electronic gate-  
22                  way is completed, except that a submission or  
23                  master file that arrives on a weekend, Federal  
24                  holiday, or day when the Food and Drug Ad-  
25                  ministration office that will review that submis-

1 sion is not otherwise open for business shall be  
2 deemed to be submitted on the next day when  
3 that office is open for business; and

4 “(B) if it is submitted in physical media  
5 form, on the day it arrives at the appropriate  
6 designated document room of the Food and  
7 Drug Administration.

8 “(b) FEE REVENUE AMOUNTS.—

9 “(1) IN GENERAL.—

10 “(A) FISCAL YEAR 2013.—For fiscal year  
11 2013, fees under subsection (a) shall be estab-  
12 lished to generate a total estimated revenue  
13 amount under such subsection of \$299,000,000.  
14 Of that amount—

15 “(i) \$50,000,000 shall be generated  
16 by the one-time backlog fee for generic  
17 drug applications pending on October 1,  
18 2012, established in subsection (a)(1); and

19 “(ii) \$249,000,000 shall be generated  
20 by the fees under paragraphs (2) through  
21 (4) of subsection (a).

22 “(B) FISCAL YEARS 2014 THROUGH 2017.—  
23 For each of the fiscal years 2014 through 2017,  
24 fees under paragraphs (2) through (4) of sub-  
25 section (a) shall be established to generate a

1 total estimated revenue amount under such sub-  
2 section that is equal to \$299,000,000, as ad-  
3 justed pursuant to subsection (c).

4 “(2) TYPES OF FEES.—In establishing fees  
5 under paragraph (1) to generate the revenue  
6 amounts specified in paragraph (1)(A)(ii) for fiscal  
7 year 2013 and paragraph (1)(B) for each of fiscal  
8 years 2014 through 2017, such fees shall be derived  
9 from the fees under paragraphs (2) through (4) of  
10 subsection (a) as follows:

11 “(A) 6 percent shall be derived from fees  
12 under subsection (a)(2) (relating to drug mas-  
13 ter files).

14 “(B) 24 percent shall be derived from fees  
15 under subsection (a)(3) (relating to abbreviated  
16 new drug applications and supplements). The  
17 amount of a fee for a prior approval supplement  
18 shall be half the amount of the fee for an ab-  
19 breviated new drug application.

20 “(C) 56 percent shall be derived from fees  
21 under subsection (a)(4)(A)(i) (relating to ge-  
22 neric drug facilities). The amount of the fee for  
23 a facility located outside the United States and  
24 its territories and possessions shall be not less  
25 than \$15,000 and not more than \$30,000 high-

er than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States, including its territories and possessions, and those located outside of the United States and its territories and possessions.

“(D) 14 percent shall be derived from fees under subsection (a)(4)(A)(ii) (relating to active pharmaceutical ingredient facilities). The amount of the fee for a facility located outside the United States and its territories and possessions shall be not less than \$15,000 and not more than \$30,000 higher than the amount of the fee for a facility located in the United States, including its territories and possessions, as determined by the Secretary on the basis of data concerning the difference in cost between inspections of facilities located in the United States and its territories and possessions and those located outside of the United States and its territories and possessions.

“(c) ADJUSTMENTS.—

1           “(1) INFLATION ADJUSTMENT.—For fiscal year  
2           2014 and subsequent fiscal years, the revenues es-  
3           tablished in subsection (b) shall be adjusted by the  
4           Secretary by notice, published in the Federal Reg-  
5           ister, for a fiscal year, by an amount equal to the  
6           sum of—

7                   “(A) one;

8                   “(B) the average annual percent change in  
9           the cost, per full-time equivalent position of the  
10          Food and Drug Administration, of all personnel  
11          compensation and benefits paid with respect to  
12          such positions for the first 3 years of the pre-  
13          ceding 4 fiscal years multiplied by the propor-  
14          tion of personnel compensation and benefits  
15          costs to total costs of human generic drug ac-  
16          tivities for the first 3 years of the preceding 4  
17          fiscal years; and

18                  “(C) the average annual percent change  
19          that occurred in the Consumer Price Index for  
20          urban consumers (Washington-Baltimore, DC–  
21          MD–VA–WV; Not Seasonally Adjusted; All  
22          items; Annual Index) for the first 3 years of the  
23          preceding 4 years of available data multiplied  
24          by the proportion of all costs other than per-  
25          sonnel compensation and benefits costs to total

1 costs of human generic drug activities for the  
2 first 3 years of the preceding 4 fiscal years.

3 The adjustment made each fiscal year under this  
4 subsection shall be added on a compounded basis to  
5 the sum of all adjustments made each fiscal year  
6 after fiscal year 2013 under this subsection.

7 “(2) FINAL YEAR ADJUSTMENT.—For fiscal  
8 year 2017, the Secretary may, in addition to adjust-  
9 ments under paragraph (1), further increase the fee  
10 revenues and fees established in subsection (b) if  
11 such an adjustment is necessary to provide for not  
12 more than 3 months of operating reserves of carry-  
13 over user fees for human generic drug activities for  
14 the first 3 months of fiscal year 2018. Such fees  
15 may only be used in fiscal year 2018. If such an ad-  
16 justment is necessary, the rationale for the amount  
17 of the increase shall be contained in the annual no-  
18 tice establishing fee revenues and fees for fiscal year  
19 2017. If the Secretary has carryover balances for  
20 such activities in excess of 3 months of such oper-  
21 ating reserves, the adjustment under this subpara-  
22 graph shall not be made.

23 “(d) ANNUAL FEE SETTING.—

24 “(1) FISCAL YEAR 2013.—For fiscal year  
25 2013—

1           “(A) the Secretary shall establish, by Octo-  
2           ber 31, 2012, the one-time generic drug backlog  
3           fee for generic drug applications pending on Oc-  
4           tober 1, 2012, the drug master file fee, the ab-  
5           breviated new drug application fee, and the  
6           prior approval supplement fee under subsection  
7           (a), based on the revenue amounts established  
8           under subsection (b); and

9           “(B) the Secretary shall establish, not  
10          later than 45 days after the date to comply  
11          with the requirement for identification of facili-  
12          ties in subsection (f)(2), the generic drug facil-  
13          ity fee and active pharmaceutical ingredient fa-  
14          cility fee under subsection (a) based on the rev-  
15          enue amounts established under subsection (b).

16          “(2) FISCAL YEARS 2014 THROUGH 2017.—Not  
17          more than 60 days before the first day of each of  
18          fiscal years 2014 through 2017, the Secretary shall  
19          establish the drug master file fee, the abbreviated  
20          new drug application fee, the prior approval supple-  
21          ment fee, the generic drug facility fee, and the active  
22          pharmaceutical ingredient facility fee under sub-  
23          section (a) for such fiscal year, based on the revenue  
24          amounts established under subsection (b) and the  
25          adjustments provided under subsection (c).



1           “(3) FEE FOR ACTIVE PHARMACEUTICAL IN-  
2           GREDIENT INFORMATION NOT INCLUDED BY REF-  
3           ERENCE TO TYPE II ACTIVE PHARMACEUTICAL IN-  
4           GREDIENT DRUG MASTER FILE.—In establishing the  
5           fees under paragraphs (1) and (2), the amount of  
6           the fee under subsection (a)(3)(F) shall be deter-  
7           mined by multiplying—

8           “(A) the sum of—

9           “(i) the total number of such active  
10           pharmaceutical ingredients in such submis-  
11           sion; and

12           “(ii) for each such ingredient that is  
13           manufactured at more than one such facil-  
14           ity, the total number of such additional fa-  
15           cilities; and

16           “(B) the amount equal to the drug master  
17           file fee established in subsection (a)(2) for such  
18           submission.

19           “(e) LIMIT.—The total amount of fees charged, as  
20           adjusted under subsection (c), for a fiscal year may not  
21           exceed the total costs for such fiscal year for the resources  
22           allocated for human generic drug activities.

23           “(f) IDENTIFICATION OF FACILITIES.—

24           “(1) PUBLICATION OF NOTICE; DEADLINE FOR  
25           COMPLIANCE.—Not later than October 1, 2012, the

1 Secretary shall cause to be published in the Federal  
2 Register a notice requiring each person that owns a  
3 facility described in subsection (a)(4)(A), or a site or  
4 organization required to be identified by paragraph  
5 (4), to submit to the Secretary information on the  
6 identity of each such facility, site, or organization.  
7 The notice required by this paragraph shall specify  
8 the type of information to be submitted and the  
9 means and format for submission of such informa-  
10 tion.

11 “(2) REQUIRED SUBMISSION OF FACILITY  
12 IDENTIFICATION.—Each person that owns a facility  
13 described in subsection (a)(4)(A) or a site or organi-  
14 zation required to be identified by paragraph (4)  
15 shall submit to the Secretary the information re-  
16 quired under this subsection each year. Such infor-  
17 mation shall—

18 “(A) for fiscal year 2013, be submitted not  
19 later than 60 days after the publication of the  
20 notice under paragraph (1); and

21 “(B) for each subsequent fiscal year, be  
22 submitted, updated, or reconfirmed on or before  
23 June 1 of the previous year.

1           “(3) CONTENTS OF NOTICE.—At a minimum,  
2           the submission required by paragraph (2) shall in-  
3           clude for each such facility—

4                   “(A) identification of a facility identified or  
5                   intended to be identified in an approved or  
6                   pending generic drug submission;

7                   “(B) whether the facility manufactures ac-  
8                   tive pharmaceutical ingredients or finished dos-  
9                   age forms, or both;

10                  “(C) whether or not the facility is located  
11                  within the United States and its territories and  
12                  possessions;

13                  “(D) whether the facility manufactures  
14                  positron emission tomography drugs solely, or  
15                  in addition to other drugs; and

16                  “(E) whether the facility manufactures  
17                  drugs that are not generic drugs.

18           “(4) CERTAIN SITES AND ORGANIZATIONS.—

19                   “(A) IN GENERAL.—Any person that owns  
20                   or operates a site or organization described in  
21                   subparagraph (B) shall submit to the Secretary  
22                   information concerning the ownership, name,  
23                   and address of the site or organization.

24                   “(B) SITES AND ORGANIZATIONS.—A site  
25                   or organization is described in this subpara-

graph if it is identified in a generic drug submission and is—

“(i) a site in which a bioanalytical study is conducted;

“(ii) a clinical research organization;

“(iii) a contract analytical testing site;

or

“(iv) a contract repackager site.

“(C) NOTICE.—The Secretary may, by notice published in the Federal Register, specify the means and format for submission of the information under subparagraph (A) and may specify, as necessary for purposes of this section, any additional information to be submitted.

“(D) INSPECTION AUTHORITY.—The Secretary’s inspection authority under section 704(a)(1) shall extend to all such sites and organizations.

“(g) EFFECT OF FAILURE TO PAY FEES.—

“(1) GENERIC DRUG BACKLOG FEE.—Failure to pay the fee under subsection (a)(1) shall result in the Secretary placing the person that owns the abbreviated new drug application subject to that fee on an arrears list, such that no new abbreviated new

1 drug applications or supplement submitted on or  
2 after October 1, 2012, from that person, or any af-  
3 filiate of that person, will be received within the  
4 meaning of section 505(j)(5)(A) until such out-  
5 standing fee is paid.

6 “(2) DRUG MASTER FILE FEE.—

7 “(A) Failure to pay the fee under sub-  
8 section (a)(2) within 20 calendar days after the  
9 applicable due date under subparagraph (E) of  
10 such subsection (as described in subsection  
11 (a)(2)(D)(ii)(I)) shall result in the Type II ac-  
12 tive pharmaceutical ingredient drug master file  
13 not being deemed available for reference.

14 “(B)(i) Any generic drug submission sub-  
15 mitted on or after October 1, 2012, that ref-  
16 erences, by a letter of authorization, a Type II  
17 active pharmaceutical ingredient drug master  
18 file that has not been deemed available for ref-  
19 erence shall not be received within the meaning  
20 of section 505(j)(5)(A) unless the condition  
21 specified in clause (ii) is met.

22 “(ii) The condition specified in this clause  
23 is that the fee established under subsection  
24 (a)(2) has been paid within 20 calendar days of  
25 the Secretary providing the notification to the

1 sponsor of the abbreviated new drug application  
2 or supplement of the failure of the owner of the  
3 Type II active pharmaceutical ingredient drug  
4 master file to pay the drug master file fee as  
5 specified in subparagraph (C).

6 “(C)(i) If an abbreviated new drug applica-  
7 tion or supplement to an abbreviated new drug  
8 application references a Type II active pharma-  
9 ceutical ingredient drug master file for which a  
10 fee under subsection (a)(2)(A) has not been  
11 paid by the applicable date under subsection  
12 (a)(2)(E), the Secretary shall notify the sponsor  
13 of the abbreviated new drug application or sup-  
14 plement of the failure of the owner of the Type  
15 II active pharmaceutical ingredient drug master  
16 file to pay the applicable fee.

17 “(ii) If such fee is not paid within 20 cal-  
18 endar days of the Secretary providing the noti-  
19 fication, the abbreviated new drug application  
20 or supplement to an abbreviated new drug ap-  
21 plication shall not be received within the mean-  
22 ing of 505(j)(5)(A).

23 “(3) ABBREVIATED NEW DRUG APPLICATION  
24 FEE AND PRIOR APPROVAL SUPPLEMENT FEE.—  
25 Failure to pay a fee under subparagraph (A) or (F)

1 of subsection (a)(3) within 20 calendar days of the  
2 applicable due date under subparagraph (C) of such  
3 subsection shall result in the abbreviated new drug  
4 application or the prior approval supplement to an  
5 abbreviated new drug application not being received  
6 within the meaning of section 505(j)(5)(A) until  
7 such outstanding fee is paid.

8 “(4) GENERIC DRUG FACILITY FEE AND ACTIVE  
9 PHARMACEUTICAL INGREDIENT FACILITY FEE.—

10 “(A) IN GENERAL.—Failure to pay the fee  
11 under subsection (a)(4) within 20 calendar days  
12 of the due date as specified in subparagraph  
13 (D) of such subsection shall result in the fol-  
14 lowing:

15 “(i) The Secretary shall place the fa-  
16 cility on a publicly available arrears list,  
17 such that no new abbreviated new drug ap-  
18 plication or supplement submitted on or  
19 after October 1, 2012, from the person  
20 that is responsible for paying such fee, or  
21 any affiliate of that person, will be received  
22 within the meaning of section 505(j)(5)(A).

23 “(ii) Any new generic drug submission  
24 submitted on or after October 1, 2012,  
25 that references such a facility shall not be

1 received, within the meaning of section  
2 505(j)(5)(A) if the outstanding facility fee  
3 is not paid within 20 calendar days of the  
4 Secretary providing the notification to the  
5 sponsor of the failure of the owner of the  
6 facility to pay the facility fee under sub-  
7 section (a)(4)(C).

8 “(iii) All drugs or active pharma-  
9 ceutical ingredients manufactured in such  
10 a facility or containing an ingredient man-  
11 ufactured in such a facility shall be deemed  
12 misbranded under section 502(aa).

13 “(B) APPLICATION OF PENALTIES.—The  
14 penalties under this paragraph shall apply until  
15 the fee established by subsection (a)(4) is paid  
16 or the facility is removed from all generic drug  
17 submissions that refer to the facility.

18 “(C) NONRECEIVAL FOR NONPAYMENT.—

19 “(i) NOTICE.—If an abbreviated new  
20 drug application or supplement to an ab-  
21 breviated new drug application submitted  
22 on or after October 1, 2012, references a  
23 facility for which a facility fee has not been  
24 paid by the applicable date under sub-  
25 section (a)(4)(C), the Secretary shall notify



1 the sponsor of the generic drug submission  
2 of the failure of the owner of the facility  
3 to pay the facility fee.

4 “(ii) NONRECEIVAL.—If the facility  
5 fee is not paid within 20 calendar days of  
6 the Secretary providing the notification  
7 under clause (i), the abbreviated new drug  
8 application or supplement to an abbrevi-  
9 ated new drug application shall not be re-  
10 ceived within the meaning of section  
11 505(j)(5)(A).

12 “(h) LIMITATIONS.—

13 “(1) IN GENERAL.—Fees under subsection (a)  
14 shall be refunded for a fiscal year beginning after  
15 fiscal year 2012, unless appropriations for salaries  
16 and expenses of the Food and Drug Administration  
17 for such fiscal year (excluding the amount of fees  
18 appropriated for such fiscal year) are equal to or  
19 greater than the amount of appropriations for the  
20 salaries and expenses of the Food and Drug Admin-  
21 istration for the fiscal year 2009 (excluding the  
22 amount of fees appropriated for such fiscal year)  
23 multiplied by the adjustment factor (as defined in  
24 section 744A) applicable to the fiscal year involved.

1           “(2) AUTHORITY.—If the Secretary does not  
2       assess fees under subsection (a) during any portion  
3       of a fiscal year and if at a later date in such fiscal  
4       year the Secretary may assess such fees, the Sec-  
5       retary may assess and collect such fees, without any  
6       modification in the rate, for Type II active pharma-  
7       ceutical ingredient drug master files, abbreviated  
8       new drug applications and prior approval supple-  
9       ments, and generic drug facilities and active phar-  
10      maceutical ingredient facilities at any time in such  
11      fiscal year notwithstanding the provisions of sub-  
12      section (a) relating to the date fees are to be paid.

13      “(i) CREDITING AND AVAILABILITY OF FEES.—

14           “(1) IN GENERAL.—Fees authorized under sub-  
15      section (a) shall be collected and available for obliga-  
16      tion only to the extent and in the amount provided  
17      in advance in appropriations Acts, subject to para-  
18      graph (2). Such fees are authorized to remain avail-  
19      able until expended. Such sums as may be necessary  
20      may be transferred from the Food and Drug Admin-  
21      istration salaries and expenses appropriation account  
22      without fiscal year limitation to such appropriation  
23      account for salaries and expenses with such fiscal  
24      year limitation. The sums transferred shall be avail-  
25      able solely for human generic drug activities.

1           “(2)   COLLECTIONS   AND   APPROPRIATION  
2   ACTS.—

3           “(A) IN GENERAL.—The fees authorized  
4   by this section—

5                   “(i) subject to subparagraphs (C) and  
6                   (D), shall be collected and available in each  
7                   fiscal year in an amount not to exceed the  
8                   amount specified in appropriation Acts, or  
9                   otherwise made available for obligation for  
10                  such fiscal year; and

11                   “(ii) shall be available for a fiscal year  
12                  beginning after fiscal year 2012 to defray  
13                  the costs of human generic drug activities  
14                  (including such costs for an additional  
15                  number of full-time equivalent positions in  
16                  the Department of Health and Human  
17                  Services to be engaged in such activities),  
18                  only if the Secretary allocates for such  
19                  purpose an amount for such fiscal year  
20                  (excluding amounts from fees collected  
21                  under this section) no less than  
22                  \$97,000,000 multiplied by the adjustment  
23                  factor defined in section 744A(3) applica-  
24                  ble to the fiscal year involved.

1           “(B) COMPLIANCE.—The Secretary shall  
2           be considered to have met the requirements of  
3           subparagraph (A)(ii) in any fiscal year if the  
4           costs funded by appropriations and allocated for  
5           human generic activities are not more than 10  
6           percent below the level specified in such sub-  
7           paragraph.

8           “(C) FEE COLLECTION DURING FIRST  
9           PROGRAM YEAR.—Until the date of enactment  
10          of an Act making appropriations through Sep-  
11          tember 30, 2013 for the salaries and expenses  
12          account of the Food and Drug Administration,  
13          fees authorized by this section for fiscal year  
14          2013, may be collected and shall be credited to  
15          such account and remain available until ex-  
16          pended.

17          “(D) PROVISION FOR EARLY PAYMENTS IN  
18          SUBSEQUENT YEARS.—Payment of fees author-  
19          ized under this section for a fiscal year (after  
20          fiscal year 2013), prior to the due date for such  
21          fees, may be accepted by the Secretary in ac-  
22          cordance with authority provided in advance in  
23          a prior year appropriations Act.

24          “(3) AUTHORIZATION OF APPROPRIATIONS.—  
25          For each of the fiscal years 2013 through 2017,

1       there is authorized to be appropriated for fees under  
2       this section an amount equivalent to the total rev-  
3       enue amount determined under subsection (b) for  
4       the fiscal year, as adjusted under subsection (c), if  
5       applicable, or as otherwise affected under paragraph  
6       (2) of this subsection.

7       “(j) COLLECTION OF UNPAID FEES.—In any case  
8       where the Secretary does not receive payment of a fee as-  
9       sessed under subsection (a) within 30 calendar days after  
10      it is due, such fee shall be treated as a claim of the United  
11      States Government subject to subchapter II of chapter 37  
12      of title 31, United States Code.

13      “(k) CONSTRUCTION.—This section may not be con-  
14      strued to require that the number of full-time equivalent  
15      positions in the Department of Health and Human Serv-  
16      ices, for officers, employees, and advisory committees not  
17      engaged in human generic drug activities, be reduced to  
18      offset the number of officers, employees, and advisory  
19      committees so engaged.

20      “(l) POSITRON EMISSION TOMOGRAPHY DRUGS.—

21              “(1) EXEMPTION FROM FEES.—Submission of  
22      an application for a positron emission tomography  
23      drug or active pharmaceutical ingredient for a  
24      positron emission tomography drug shall not require  
25      the payment of any fee under this section. Facilities

1       that solely produce positron emission tomography  
2       drugs shall not be required to pay a facility fee as  
3       established in subsection (a)(4).

4           “(2) IDENTIFICATION REQUIREMENT.—Facili-  
5       ties that produce positron emission tomography  
6       drugs or active pharmaceutical ingredients of such  
7       drugs are required to be identified pursuant to sub-  
8       section (f).

9           “(m) DISPUTES CONCERNING FEES.—To qualify for  
10      the return of a fee claimed to have been paid in error  
11      under this section, a person shall submit to the Secretary  
12      a written request justifying such return within 180 cal-  
13      endar days after such fee was paid.

14          “(n) SUBSTANTIALLY COMPLETE APPLICATIONS.—  
15      An abbreviated new drug application that is not consid-  
16      ered to be received within the meaning of section  
17      505(j)(5)(A) because of failure to pay an applicable fee  
18      under this provision within the time period specified in  
19      subsection (g) shall be deemed not to have been ‘substan-  
20      tially complete’ on the date of its submission within the  
21      meaning of section 505(j)(5)(B)(iv)(II)(cc). An abbre-  
22      viated new drug application that is not substantially com-  
23      plete on the date of its submission solely because of failure  
24      to pay an applicable fee under the preceding sentence shall  
25      be deemed substantially complete and received within the

1 meaning of section 505(j)(5)(A) as of the date such appli-  
 2 cable fee is received.”.

3 **SEC. 303. REAUTHORIZATION; REPORTING REQUIREMENTS.**

4 Part 7 of subchapter C of chapter VII, as added by  
 5 section 302 of this Act, is amended by inserting after sec-  
 6 tion 744B the following:

7 **“SEC. 744C. REAUTHORIZATION; REPORTING REQUIRE-**  
 8 **MENTS.**

9 “(a) PERFORMANCE REPORT.—

10 “(1) IN GENERAL.—Beginning with fiscal year  
 11 2013, not later than 120 days after the end of each  
 12 fiscal year for which fees are collected under this  
 13 part, the Secretary shall prepare and submit to the  
 14 Committee on Energy and Commerce of the House  
 15 of Representatives and the Committee on Health,  
 16 Education, Labor, and Pensions of the Senate a re-  
 17 port concerning the progress of the Food and Drug  
 18 Administration in achieving the goals identified in  
 19 the letters described in section 301(b) of the Generic  
 20 Drug User Fee Amendments of 2012 during such  
 21 fiscal year and the future plans of the Food and  
 22 Drug Administration for meeting the goals.

23 “(2) REGULATORY SCIENCE ACCOUNTABILITY  
 24 METRICS.—The report required by paragraph (1)  
 25 shall describe the amounts spent, data generated,

1 and activities undertaken, including any FDA Advi-  
2 sory Committee consideration, by the Secretary for  
3 each of the local acting bioequivalence topics (Topics  
4 1–3) in the Regulatory Science Plan described in the  
5 letters described in section 301(b) of the Generic  
6 Drug User Fee Amendments of 2012.

7 “(b) FISCAL REPORT.—Beginning with fiscal year  
8 2013, not later than 120 days after the end of each fiscal  
9 year for which fees are collected under this part, the Sec-  
10 retary shall prepare and submit to the Committee on En-  
11 ergy and Commerce of the House of Representatives and  
12 the Committee on Health, Education, Labor, and Pen-  
13 sions of the Senate a report on the implementation of the  
14 authority for such fees during such fiscal year and the  
15 use, by the Food and Drug Administration, of the fees  
16 collected for such fiscal year.

17 “(c) PUBLIC AVAILABILITY.—The Secretary shall  
18 make the reports required under subsections (a) and (b)  
19 available to the public on the Internet Web site of the  
20 Food and Drug Administration.

21 “(d) REAUTHORIZATION.—

22 “(1) CONSULTATION.—In developing rec-  
23 ommendations to present to the Congress with re-  
24 spect to the goals, and plans for meeting the goals,  
25 for human generic drug activities for the first 5 fis-



1 cal years after fiscal year 2017, and for the reau-  
2 thorization of this part for such fiscal years, the Sec-  
3 retary shall consult with—

4 “(A) the Committee on Energy and Com-  
5 merce of the House of Representatives;

6 “(B) the Committee on Health, Education,  
7 Labor, and Pensions of the Senate;

8 “(C) scientific and academic experts;

9 “(D) health care professionals;

10 “(E) representatives of patient and con-  
11 sumer advocacy groups; and

12 “(F) the generic drug industry.

13 “(2) PRIOR PUBLIC INPUT.—Prior to beginning  
14 negotiations with the generic drug industry on the  
15 reauthorization of this part, the Secretary shall—

16 “(A) publish a notice in the Federal Reg-  
17 ister requesting public input on the reauthoriza-  
18 tion;

19 “(B) hold a public meeting at which the  
20 public may present its views on the reauthoriza-  
21 tion, including specific suggestions for changes  
22 to the goals referred to in subsection (a);

23 “(C) provide a period of 30 days after the  
24 public meeting to obtain written comments from  
25 the public suggesting changes to this part; and

1           “(D) publish the comments on the Food  
2           and Drug Administration’s Internet Web site.

3           “(3) PERIODIC CONSULTATION.—Not less fre-  
4           quently than once every month during negotiations  
5           with the generic drug industry, the Secretary shall  
6           hold discussions with representatives of patient and  
7           consumer advocacy groups to continue discussions of  
8           their views on the reauthorization and their sugges-  
9           tions for changes to this part as expressed under  
10          paragraph (2).

11          “(4) PUBLIC REVIEW OF RECOMMENDA-  
12          TIONS.—After negotiations with the generic drug in-  
13          dustry, the Secretary shall—

14               “(A) present the recommendations devel-  
15               oped under paragraph (1) to the congressional  
16               committees specified in such paragraph;

17               “(B) publish such recommendations in the  
18               Federal Register;

19               “(C) provide for a period of 30 days for  
20               the public to provide written comments on such  
21               recommendations;

22               “(D) hold a meeting at which the public  
23               may present its views on such recommenda-  
24               tions; and

1           “(E) after consideration of such public  
2           views and comments, revise such recommenda-  
3           tions as necessary.

4           “(5) TRANSMITTAL OF RECOMMENDATIONS.—  
5           Not later than January 15, 2017, the Secretary  
6           shall transmit to the Congress the revised rec-  
7           ommendations under paragraph (4), a summary of  
8           the views and comments received under such para-  
9           graph, and any changes made to the recommenda-  
10          tions in response to such views and comments.

11          “(6) MINUTES OF NEGOTIATION MEETINGS.—

12                 “(A) PUBLIC AVAILABILITY.—Before pre-  
13                 senting the recommendations developed under  
14                 paragraphs (1) through (5) to the Congress, the  
15                 Secretary shall make publicly available, on the  
16                 Internet Web site of the Food and Drug Ad-  
17                 ministration, minutes of all negotiation meet-  
18                 ings conducted under this subsection between  
19                 the Food and Drug Administration and the ge-  
20                 neric drug industry.

21                 “(B) CONTENT.—The minutes described  
22                 under subparagraph (A) shall summarize any  
23                 substantive proposal made by any party to the  
24                 negotiations as well as significant controversies

1           or differences of opinion during the negotiations  
2           and their resolution.”.

3 **SEC. 304. SUNSET DATES.**

4           (a) AUTHORIZATION.—Sections 744A and 744B, as  
5 added by section 302 of this Act, are repealed October  
6 1, 2017.

7           (b) REPORTING REQUIREMENTS.—Section 744C, as  
8 added by section 303 of this Act, is repealed January 31,  
9 2018.

10 **SEC. 305. EFFECTIVE DATE.**

11           The amendments made by this title shall take effect  
12 on October 1, 2012, or the date of the enactment of this  
13 title, whichever is later, except that fees under section 302  
14 shall be assessed for all human generic drug submissions  
15 and Type II active pharmaceutical drug master files re-  
16 ceived on or after October 1, 2012, regardless of the date  
17 of enactment of this title.

18 **SEC. 306. AMENDMENT WITH RESPECT TO MISBRANDING.**

19           Section 502 (21 U.S.C. 352) is amended by adding  
20 at the end the following:

21           “(aa) If it is a drug, or an active pharmaceutical in-  
22 gredient, and it was manufactured, prepared, propagated,  
23 compounded, or processed in a facility for which fees have  
24 not been paid as required by section 744A(a)(4) or for  
25 which identifying information required by section 744B(f)

1 has not been submitted, or it contains an active pharma-  
2 ceutical ingredient that was manufactured, prepared,  
3 propagated, compounded, or processed in such a facility.”.

4 **SEC. 307. STREAMLINED HIRING AUTHORITY TO SUPPORT**  
5 **ACTIVITIES RELATED TO HUMAN GENERIC**  
6 **DRUGS.**

7 Section 714, as added by section 208 of this Act, is  
8 amended—

9 (1) by amending subsection (b) to read as fol-  
10 lows:

11 “(b) **ACTIVITIES DESCRIBED.**—The activities de-  
12 scribed in this subsection are—

13 “(1) activities under this Act related to the  
14 process for the review of device applications (as de-  
15 fined in section 737(8)); and

16 “(2) activities under this Act related to human  
17 generic drug activities (as defined in section  
18 744A).”; and

19 (2) by amending subsection (c) to read as fol-  
20 lows:

21 “(c) **OBJECTIVES SPECIFIED.**—The objectives speci-  
22 fied in this subsection are—

23 “(1) with respect to the activities under sub-  
24 section (b)(1), the goals referred to in section  
25 738A(a)(1); and

1           “(2) with respect to the activities under sub-  
2           section (b)(2), the goals referred to in section  
3           744C(a).”.

4   **TITLE IV—FEES RELATING TO**  
5       **BIOSIMILAR           BIOLOGICAL**  
6       **PRODUCTS**

7   **SEC. 401. SHORT TITLE; FINDING.**

8           (a) **SHORT TITLE.**—This title may be cited as the  
9    “Biosimilar User Fee Act of 2012”.

10          (b) **FINDING.**—The Congress finds that the fees au-  
11   thorized by the amendments made in this title will be dedi-  
12   cated to expediting the process for the review of biosimilar  
13   biological product applications, including postmarket safe-  
14   ty activities, as set forth in the goals identified for pur-  
15   poses of part 8 of subchapter C of chapter VII of the Fed-  
16   eral Food, Drug, and Cosmetic Act, in the letters from  
17   the Secretary of Health and Human Services to the Chair-  
18   man of the Committee on Health, Education, Labor, and  
19   Pensions of the Senate and the Chairman of the Com-  
20   mittee on Energy and Commerce of the House of Rep-  
21   resentatives, as set forth in the Congressional Record.

1 **SEC. 402. FEES RELATING TO BIOSIMILAR BIOLOGICAL**  
2 **PRODUCTS.**

3 Subchapter C of chapter VII (21 U.S.C. 379f et seq.)  
4 is amended by inserting after part 7, as added by title  
5 III of this Act, the following:

6 **“PART 8—FEES RELATING TO BIOSIMILAR**  
7 **BIOLOGICAL PRODUCTS**

8 **“SEC. 744G. DEFINITIONS.**

9 “For purposes of this part:

10 “(1) The term ‘adjustment factor’ applicable to  
11 a fiscal year that is the Consumer Price Index for  
12 all urban consumers (Washington-Baltimore, DC–  
13 MD–VA–WV; Not Seasonally Adjusted; All items) of  
14 the preceding fiscal year divided by such Index for  
15 September 2011.

16 “(2) The term ‘affiliate’ means a business enti-  
17 ty that has a relationship with a second business en-  
18 tity if, directly or indirectly—

19 “(A) one business entity controls, or has  
20 the power to control, the other business entity;  
21 or

22 “(B) a third party controls, or has power  
23 to control, both of the business entities.

24 “(3) The term ‘biosimilar biological product’  
25 means a product for which a biosimilar biological  
26 product application has been approved.

1           “(4)(A) Subject to subparagraph (B), the term  
2           ‘biosimilar biological product application’ means an  
3           application for licensure of a biological product  
4           under section 351(k) of the Public Health Service  
5           Act.

6           “(B) Such term does not include—

7                   “(i) a supplement to such an application;

8                   “(ii) an application filed under section  
9                   351(k) of the Public Health Service Act that  
10                  cites as the reference product a bovine blood  
11                  product for topical application licensed before  
12                  September 1, 1992, or a large volume paren-  
13                  teral drug product approved before such date;

14                  “(iii) an application filed under section  
15                  351(k) of the Public Health Service Act with  
16                  respect to—

17                          “(I) whole blood or a blood component  
18                          for transfusion;

19                          “(II) an allergenic extract product;

20                          “(III) an in vitro diagnostic biological  
21                          product; or

22                          “(IV) a biological product for further  
23                          manufacturing use only; or

24                          “(iv) an application for licensure under  
25                          section 351(k) of the Public Health Service Act



1           that is submitted by a State or Federal Govern-  
2           ment entity for a product that is not distributed  
3           commercially.

4           “(5) The term ‘biosimilar biological product de-  
5           velopment meeting’ means any meeting, other than  
6           a biosimilar initial advisory meeting, regarding the  
7           content of a development program, including a pro-  
8           posed design for, or data from, a study intended to  
9           support a biosimilar biological product application.

10          “(6) The term ‘biosimilar biological product de-  
11          velopment program’ means the program under this  
12          part for expediting the process for the review of sub-  
13          missions in connection with biosimilar biological  
14          product development.

15          “(7)(A) The term ‘biosimilar biological product  
16          establishment’ means a foreign or domestic place of  
17          business—

18                 “(i) that is at one general physical location  
19                 consisting of one or more buildings, all of which  
20                 are within five miles of each other; and

21                 “(ii) at which one or more biosimilar bio-  
22                 logical products are manufactured in final dos-  
23                 age form.

24          “(B) For purposes of subparagraph (A)(ii), the  
25          term ‘manufactured’ does not include packaging.

1           “(8) The term ‘biosimilar initial advisory meet-  
2       ing’—

3           “(A) means a meeting, if requested, that is  
4       limited to—

5           “(i) a general discussion regarding  
6       whether licensure under section 351(k) of  
7       the Public Health Service Act may be fea-  
8       sible for a particular product; and

9           “(ii) if so, general advice on the ex-  
10      pected content of the development pro-  
11      gram; and

12          “(B) does not include any meeting that in-  
13      volves substantive review of summary data or  
14      full study reports.

15          “(9) The term ‘costs of resources allocated for  
16      the process for the review of biosimilar biological  
17      product applications’ means the expenses in connec-  
18      tion with the process for the review of biosimilar bio-  
19      logical product applications for—

20          “(A) officers and employees of the Food  
21      and Drug Administration, contractors of the  
22      Food and Drug Administration, advisory com-  
23      mittees, and costs related to such officers em-  
24      ployees and committees and to contracts with  
25      such contractors;

1           “(B) management of information, and the  
2           acquisition, maintenance, and repair of com-  
3           puter resources;

4           “(C) leasing, maintenance, renovation, and  
5           repair of facilities and acquisition, maintenance,  
6           and repair of fixtures, furniture, scientific  
7           equipment, and other necessary materials and  
8           supplies; and

9           “(D) collecting fees under section 744H  
10          and accounting for resources allocated for the  
11          review of submissions in connection with bio-  
12          similar biological product development, bio-  
13          similar biological product applications, and sup-  
14          plements.

15          “(10) The term ‘final dosage form’ means, with  
16          respect to a biosimilar biological product, a finished  
17          dosage form which is approved for administration to  
18          a patient without substantial further manufacturing  
19          (such as lyophilized products before reconstitution).

20          “(11) The term ‘financial hold’—

21                 “(A) means an order issued by the Sec-  
22                 retary to prohibit the sponsor of a clinical in-  
23                 vestigation from continuing the investigation if  
24                 the Secretary determines that the investigation  
25                 is intended to support a biosimilar biological

1 product application and the sponsor has failed  
2 to pay any fee for the product required under  
3 subparagraph (A), (B), or (D) of section  
4 744H(a)(1); and

5 “(B) does not mean that any of the bases  
6 for a ‘clinical hold’ under section 505(i)(3) have  
7 been determined by the Secretary to exist con-  
8 cerning the investigation.

9 “(12) The term ‘person’ includes an affiliate of  
10 such person.

11 “(13) The term ‘process for the review of bio-  
12 similar biological product applications’ means the  
13 following activities of the Secretary with respect to  
14 the review of submissions in connection with bio-  
15 similar biological product development, biosimilar bi-  
16 ological product applications, and supplements:

17 “(A) The activities necessary for the re-  
18 view of submissions in connection with bio-  
19 similar biological product development, bio-  
20 similar biological product applications, and sup-  
21 plements.

22 “(B) Actions related to submissions in con-  
23 nection with biosimilar biological product devel-  
24 opment, the issuance of action letters which ap-  
25 prove biosimilar biological product applications

1 or which set forth in detail the specific defi-  
2 ciencies in such applications, and where appro-  
3 priate, the actions necessary to place such ap-  
4 plications in condition for approval.

5 “(C) The inspection of biosimilar biological  
6 product establishments and other facilities un-  
7 dertaken as part of the Secretary’s review of  
8 pending biosimilar biological product applica-  
9 tions and supplements.

10 “(D) Activities necessary for the release of  
11 lots of biosimilar biological products under sec-  
12 tion 351(k) of the Public Health Service Act.

13 “(E) Monitoring of research conducted in  
14 connection with the review of biosimilar biologi-  
15 cal product applications.

16 “(F) Postmarket safety activities with re-  
17 spect to biologics approved under biosimilar bio-  
18 logical product applications or supplements, in-  
19 cluding the following activities:

20 “(i) Collecting, developing, and re-  
21 viewing safety information on biosimilar bi-  
22 ological products, including adverse-event  
23 reports.

1 “(ii) Developing and using improved  
2 adverse-event data-collection systems, in-  
3 cluding information technology systems.

4 “(iii) Developing and using improved  
5 analytical tools to assess potential safety  
6 problems, including access to external data  
7 bases.

8 “(iv) Implementing and enforcing sec-  
9 tion 505(o) (relating to postapproval stud-  
10 ies and clinical trials and labeling changes)  
11 and section 505(p) (relating to risk evalua-  
12 tion and mitigation strategies).

13 “(v) Carrying out section 505(k)(5)  
14 (relating to adverse-event reports and  
15 postmarket safety activities).

16 “(14) The term ‘supplement’ means a request  
17 to the Secretary to approve a change in a biosimilar  
18 biological product application which has been ap-  
19 proved, including a supplement requesting that the  
20 Secretary determine that the biosimilar biological  
21 product meets the standards for interchangeability  
22 described in section 351(k)(4) of the Public Health  
23 Service Act.

1 **“SEC. 744H. AUTHORITY TO ASSESS AND USE BIOSIMILAR**  
2 **BIOLOGICAL PRODUCT FEES.**

3 “(a) TYPES OF FEES.—Beginning in fiscal year  
4 2013, the Secretary shall assess and collect fees in accord-  
5 ance with this section as follows:

6 “(1) BIOSIMILAR DEVELOPMENT PROGRAM  
7 FEES.—

8 “(A) INITIAL BIOSIMILAR BIOLOGICAL  
9 PRODUCT DEVELOPMENT FEE.—

10 “(i) IN GENERAL.—Each person that  
11 submits to the Secretary a meeting request  
12 described under clause (ii) or a clinical  
13 protocol for an investigational new drug  
14 protocol described under clause (iii) shall  
15 pay for the product named in the meeting  
16 request or the investigational new drug ap-  
17 plication the initial biosimilar biological  
18 product development fee established under  
19 subsection (b)(1)(A).

20 “(ii) MEETING REQUEST.—The meet-  
21 ing request defined in this clause is a re-  
22 quest for a biosimilar biological product  
23 development meeting for a product.

24 “(iii) CLINICAL PROTOCOL FOR IND.—  
25 A clinical protocol for an investigational  
26 new drug protocol described in this clause

1 is a clinical protocol consistent with the  
2 provisions of section 505(i), including any  
3 regulations promulgated under section  
4 505(i), (referred to in this section as ‘in-  
5 vestigational new drug application’) de-  
6 scribing an investigation that the Secretary  
7 determines is intended to support a bio-  
8 similar biological product application for a  
9 product.

10 “(iv) DUE DATE.—The initial bio-  
11 similar biological product development fee  
12 shall be due by the earlier of the following:

13 “(I) Not later than 5 days after  
14 the Secretary grants a request for a  
15 biosimilar biological product develop-  
16 ment meeting.

17 “(II) The date of submission of  
18 an investigational new drug applica-  
19 tion describing an investigation that  
20 the Secretary determines is intended  
21 to support a biosimilar biological  
22 product application.

23 “(v) TRANSITION RULE.—Each per-  
24 son that has submitted an investigational  
25 new drug application prior to the date of



1 enactment of the Biosimilars User Fee Act  
2 of 2012 shall pay the initial biosimilar bio-  
3 logical product development fee by the ear-  
4 lier of the following:

5 “(I) Not later than 60 days after  
6 the date of the enactment of the  
7 Biosimilars User Fee Act of 2012, if  
8 the Secretary determines that the in-  
9 vestigational new drug application de-  
10 scribes an investigation that is in-  
11 tended to support a biosimilar biologi-  
12 cal product application.

13 “(II) Not later than 5 days after  
14 the Secretary grants a request for a  
15 biosimilar biological product develop-  
16 ment meeting.

17 “(B) ANNUAL BIOSIMILAR BIOLOGICAL  
18 PRODUCT DEVELOPMENT FEE.—

19 “(i) IN GENERAL.—A person that  
20 pays an initial biosimilar biological product  
21 development fee for a product shall pay for  
22 such product, beginning in the fiscal year  
23 following the fiscal year in which the initial  
24 biosimilar biological product development  
25 fee was paid, an annual fee established

1 under subsection (b)(1)(B) for biosimilar  
2 biological product development (referred to  
3 in this section as ‘annual biosimilar bio-  
4 logical product development fee’).

5 “(ii) DUE DATE.—The annual bio-  
6 similar biological product development pro-  
7 gram fee for each fiscal year will be due on  
8 the later of—

9 “(I) the first business day on or  
10 after October 1 of each such year; or

11 “(II) the first business day after  
12 the enactment of an appropriations  
13 Act providing for the collection and  
14 obligation of fees for such year under  
15 this section.

16 “(iii) EXCEPTION.—The annual bio-  
17 similar development program fee for each  
18 fiscal year will be due on the date specified  
19 in clause (ii), unless the person has—

20 “(I) submitted a marketing appli-  
21 cation for the biological product that  
22 was accepted for filing; or

23 “(II) discontinued participation  
24 in the biosimilar biological product de-

1                   velopment program for the product  
2                   under subparagraph (C).

3                   “(C) DISCONTINUATION OF FEE OBLIGA-  
4                   TION.—A person may discontinue participation  
5                   in the biosimilar biological product development  
6                   program for a product effective October 1 of a  
7                   fiscal year by, not later than August 1 of the  
8                   preceding fiscal year—

9                   “(i) if no investigational new drug ap-  
10                  plication concerning the product has been  
11                  submitted, submitting to the Secretary a  
12                  written declaration that the person has no  
13                  present intention of further developing the  
14                  product as a biosimilar biological product;  
15                  or

16                  “(ii) if an investigational new drug  
17                  application concerning the product has  
18                  been submitted, by withdrawing the inves-  
19                  tigational new drug application in accord-  
20                  ance with part 312 of title 21, Code of  
21                  Federal Regulations (or any successor reg-  
22                  ulations).

23                  “(D) REACTIVATION FEE.—

24                  “(i) IN GENERAL.—A person that has  
25                  discontinued participation in the biosimilar

1 biological product development program for  
2 a product under subparagraph (C) shall  
3 pay a fee (referred to in this section as ‘re-  
4 activation fee’) by the earlier of the fol-  
5 lowing:

6 “(I) Not later than 5 days after  
7 the Secretary grants a request for a  
8 biosimilar biological product develop-  
9 ment meeting for the product (after  
10 the date on which such participation  
11 was discontinued).

12 “(II) Upon the date of submis-  
13 sion (after the date on which such  
14 participation was discontinued) of an  
15 investigational new drug application  
16 describing an investigation that the  
17 Secretary determines is intended to  
18 support a biosimilar biological product  
19 application for that product.

20 “(ii) APPLICATION OF ANNUAL  
21 FEE.—A person that pays a reactivation  
22 fee for a product shall pay for such prod-  
23 uct, beginning in the next fiscal year, the  
24 annual biosimilar biological product devel-  
25 opment fee under subparagraph (B).

1           “(E) EFFECT OF FAILURE TO PAY BIO-  
2           SIMILAR DEVELOPMENT PROGRAM FEES.—

3           “(i) NO BIOSIMILAR BIOLOGICAL  
4           PRODUCT DEVELOPMENT MEETINGS.—If a  
5           person has failed to pay an initial or an-  
6           nual biosimilar biological product develop-  
7           ment fee as required under subparagraph  
8           (A) or (B), or a reactivation fee as re-  
9           quired under subparagraph (D), the Sec-  
10          retary shall not provide a biosimilar bio-  
11          logical product development meeting relat-  
12          ing to the product for which fees are owed.

13          “(ii) NO RECEIPT OF INVESTIGA-  
14          TIONAL NEW DRUG APPLICATIONS.—Ex-  
15          cept in extraordinary circumstances, the  
16          Secretary shall not consider an investiga-  
17          tional new drug application to have been  
18          received under section 505(i)(2) if—

19                 “(I) the Secretary determines  
20                 that the investigation is intended to  
21                 support a biosimilar biological product  
22                 application; and

23                 “(II) the sponsor has failed to  
24                 pay an initial or annual biosimilar bio-  
25                 logical product development fee for

1 the product as required under sub-  
2 paragraph (A) or (B), or a reactiva-  
3 tion fee as required under subpara-  
4 graph (D).

5 “(iii) FINANCIAL HOLD.—Notwith-  
6 standing section 505(i)(2), except in ex-  
7 traordinary circumstances, the Secretary  
8 shall prohibit the sponsor of a clinical in-  
9 vestigation from continuing the investiga-  
10 tion if—

11 “(I) the Secretary determines  
12 that the investigation is intended to  
13 support a biosimilar biological product  
14 application; and

15 “(II) the sponsor has failed to  
16 pay an initial or annual biosimilar bio-  
17 logical product development fee for  
18 the product as required under sub-  
19 paragraph (A) or (B), or a reactiva-  
20 tion fee for the product as required  
21 under subparagraph (D).

22 “(iv) NO ACCEPTANCE OF BIOSIMILAR  
23 BIOLOGICAL PRODUCT APPLICATIONS OR  
24 SUPPLEMENTS.—If a person has failed to  
25 pay an initial or annual biosimilar biologi-

1 cal product development fee as required  
2 under subparagraph (A) or (B), or a reac-  
3 tivation fee as required under subpara-  
4 graph (D), any biosimilar biological prod-  
5 uct application or supplement submitted by  
6 that person shall be considered incomplete  
7 and shall not be accepted for filing by the  
8 Secretary until all such fees owed by such  
9 person have been paid.

10 “(F) LIMITS REGARDING BIOSIMILAR DE-  
11 VELOPMENT PROGRAM FEES.—

12 “(i) NO REFUNDS.—The Secretary  
13 shall not refund any initial or annual bio-  
14 similar biological product development fee  
15 paid under subparagraph (A) or (B), or  
16 any reactivation fee paid under subpara-  
17 graph (D).

18 “(ii) NO WAIVERS, EXEMPTIONS, OR  
19 REDUCTIONS.—The Secretary shall not  
20 grant a waiver, exemption, or reduction of  
21 any initial or annual biosimilar biological  
22 product development fee due or payable  
23 under subparagraph (A) or (B), or any re-  
24 activation fee due or payable under sub-  
25 paragraph (D).

1           “(2) BIOSIMILAR BIOLOGICAL PRODUCT APPLI-  
2           CATION AND SUPPLEMENT FEE.—

3           “(A) IN GENERAL.—Each person that sub-  
4           mits, on or after October 1, 2012, a biosimilar  
5           biological product application or a supplement  
6           shall be subject to the following fees:

7           “(i) A fee for a biosimilar biological  
8           product application that is equal to—

9           “(I) the amount of the fee estab-  
10           lished under subsection (b)(1)(D) for  
11           a biosimilar biological product applica-  
12           tion; minus

13           “(II) the cumulative amount of  
14           fees paid, if any, under subparagraphs  
15           (A), (B), and (D) of paragraph (1)  
16           for the product that is the subject of  
17           the application.

18           “(ii) A fee for a biosimilar biological  
19           product application for which clinical data  
20           (other than comparative bioavailability  
21           studies) with respect to safety or effective-  
22           ness are not required, that is equal to—

23           “(I) half of the amount of the fee  
24           established under subsection (b)(1)(D)



1 for a biosimilar biological product ap-  
2 plication; minus

3 “(II) the cumulative amount of  
4 fees paid, if any, under subparagraphs  
5 (A), (B), and (D) of paragraph (1)  
6 for that product.

7 “(iii) A fee for a supplement for which  
8 clinical data (other than comparative bio-  
9 availability studies) with respect to safety  
10 or effectiveness are required, that is equal  
11 to half of the amount of the fee established  
12 under subsection (b)(1)(D) for a biosimilar  
13 biological product application.

14 “(B) REDUCTION IN FEES.—Notwith-  
15 standing section 404 of the Biosimilars User  
16 Fee Act of 2012, any person who pays a fee  
17 under subparagraph (A), (B), or (D) of para-  
18 graph (1) for a product before October 1, 2017,  
19 but submits a biosimilar biological product ap-  
20 plication for that product after such date, shall  
21 be entitled to the reduction of any biosimilar bi-  
22 ological product application fees that may be  
23 assessed at the time when such biosimilar bio-  
24 logical product application is submitted, by the  
25 cumulative amount of fees paid under subpara-

1 graphs (A), (B), and (D) of paragraph (1) for  
2 that product.

3 “(C) PAYMENT DUE DATE.—Any fee re-  
4 quired by subparagraph (A) shall be due upon  
5 submission of the application or supplement for  
6 which such fee applies.

7 “(D) EXCEPTION FOR PREVIOUSLY FILED  
8 APPLICATION OR SUPPLEMENT.—If a biosimilar  
9 biological product application or supplement  
10 was submitted by a person that paid the fee for  
11 such application or supplement, was accepted  
12 for filing, and was not approved or was with-  
13 drawn (without a waiver), the submission of a  
14 biosimilar biological product application or a  
15 supplement for the same product by the same  
16 person (or the person’s licensee, assignee, or  
17 successor) shall not be subject to a fee under  
18 subparagraph (A).

19 “(E) REFUND OF APPLICATION FEE IF AP-  
20 PPLICATION REFUSED FOR FILING OR WITH-  
21 DRAWN BEFORE FILING.—The Secretary shall  
22 refund 75 percent of the fee paid under this  
23 paragraph for any application or supplement  
24 which is refused for filing or withdrawn without  
25 a waiver before filing.

1                   “(F) FEES FOR APPLICATIONS PRE-  
2                   VIOUSLY REFUSED FOR FILING OR WITHDRAWN  
3                   BEFORE FILING.—A biosimilar biological prod-  
4                   uct application or supplement that was sub-  
5                   mitted but was refused for filing, or was with-  
6                   drawn before being accepted or refused for fil-  
7                   ing, shall be subject to the full fee under sub-  
8                   paragraph (A) upon being resubmitted or filed  
9                   over protest, unless the fee is waived under sub-  
10                  section (c).

11               “(3) BIOSIMILAR BIOLOGICAL PRODUCT ESTAB-  
12               LISHMENT FEE.—

13               “(A) IN GENERAL.—Except as provided in  
14               subparagraph (E), each person that is named  
15               as the applicant in a biosimilar biological prod-  
16               uct application shall be assessed an annual fee  
17               established under subsection (b)(1)(E) for each  
18               biosimilar biological product establishment that  
19               is listed in the approved biosimilar biological  
20               product application as an establishment that  
21               manufactures the biosimilar biological product  
22               named in such application.

23               “(B) ASSESSMENT IN FISCAL YEARS.—The  
24               establishment fee shall be assessed in each fis-  
25               cal year for which the biosimilar biological prod-

1           uct named in the application is assessed a fee  
2           under paragraph (4) unless the biosimilar bio-  
3           logical product establishment listed in the appli-  
4           cation does not engage in the manufacture of  
5           the biosimilar biological product during such  
6           fiscal year.

7           “(C) DUE DATE.—The establishment fee  
8           for a fiscal year shall be due on the later of—

9           “(i) the first business day on or after  
10          October 1 of such fiscal year; or

11          “(ii) the first business day after the  
12          enactment of an appropriations Act pro-  
13          viding for the collection and obligation of  
14          fees for such fiscal year under this section.

15          “(D) APPLICATION TO ESTABLISHMENT.—

16          “(i) Each biosimilar biological product  
17          establishment shall be assessed only one  
18          fee per biosimilar biological product estab-  
19          lishment, notwithstanding the number of  
20          biosimilar biological products manufac-  
21          tured at the establishment, subject to  
22          clause (ii).

23          “(ii) In the event an establishment is  
24          listed in a biosimilar biological product ap-  
25          plication by more than one applicant, the

1 establishment fee for the fiscal year shall  
2 be divided equally and assessed among the  
3 applicants whose biosimilar biological prod-  
4 ucts are manufactured by the establish-  
5 ment during the fiscal year and assessed  
6 biosimilar biological product fees under  
7 paragraph (4).

8 “(E) EXCEPTION FOR NEW PRODUCTS.—

9 If, during the fiscal year, an applicant initiates  
10 or causes to be initiated the manufacture of a  
11 biosimilar biological product at an establish-  
12 ment listed in its biosimilar biological product  
13 application—

14 “(i) that did not manufacture the bio-  
15 similar biological product in the previous  
16 fiscal year; and

17 “(ii) for which the full biosimilar bio-  
18 logical product establishment fee has been  
19 assessed in the fiscal year at a time before  
20 manufacture of the biosimilar biological  
21 product was begun,

22 the applicant shall not be assessed a share of  
23 the biosimilar biological product establishment  
24 fee for the fiscal year in which the manufacture  
25 of the product began.

1 “(4) BIOSIMILAR BIOLOGICAL PRODUCT FEE.—

2 “(A) IN GENERAL.—Each person who is  
3 named as the applicant in a biosimilar biological  
4 product application shall pay for each such  
5 biosimilar biological product the annual fee es-  
6 tablished under subsection (b)(1)(F).

7 “(B) DUE DATE.—The biosimilar biological  
8 product fee for a fiscal year shall be due on  
9 the later of—

10 “(i) the first business day on or after  
11 October 1 of each such year; or

12 “(ii) the first business day after the  
13 enactment of an appropriations Act pro-  
14 viding for the collection and obligation of  
15 fees for such year under this section.

16 “(C) ONE FEE PER PRODUCT PER YEAR.—  
17 The biosimilar biological product fee shall be  
18 paid only once for each product for each fiscal  
19 year.

20 “(b) FEE SETTING AND AMOUNTS.—

21 “(1) IN GENERAL.—Subject to paragraph (2),  
22 the Secretary shall, 60 days before the start of each  
23 fiscal year that begins after September 30, 2012, es-  
24 tablish, for the next fiscal year, the fees under sub-

1 section (a). Except as provided in subsection (c),  
2 such fees shall be in the following amounts:

3 “(A) INITIAL BIOSIMILAR BIOLOGICAL  
4 PRODUCT DEVELOPMENT FEE.—The initial bio-  
5 similar biological product development fee under  
6 subsection (a)(1)(A) for a fiscal year shall be  
7 equal to 10 percent of the amount established  
8 under section 736(c)(4) for a human drug ap-  
9 plication described in section 736(a)(1)(A)(i)  
10 for that fiscal year.

11 “(B) ANNUAL BIOSIMILAR BIOLOGICAL  
12 PRODUCT DEVELOPMENT FEE.—The annual  
13 biosimilar biological product development fee  
14 under subsection (a)(1)(B) for a fiscal year  
15 shall be equal to 10 percent of the amount es-  
16 tablished under section 736(c)(4) for a human  
17 drug application described in section  
18 736(a)(1)(A)(i) for that fiscal year.

19 “(C) REACTIVATION FEE.—The reactiva-  
20 tion fee under subsection (a)(1)(D) for a fiscal  
21 year shall be equal to 20 percent of the amount  
22 of the fee established under section 736(c)(4)  
23 for a human drug application described in sec-  
24 tion 736(a)(1)(A)(i) for that fiscal year.

1           “(D) BIOSIMILAR BIOLOGICAL PRODUCT  
2           APPLICATION FEE.—The biosimilar biological  
3           product application fee under subsection (a)(2)  
4           for a fiscal year shall be equal to the amount  
5           established under section 736(c)(4) for a  
6           human drug application described in section  
7           736(a)(1)(A)(i) for that fiscal year.

8           “(E) BIOSIMILAR BIOLOGICAL PRODUCT  
9           ESTABLISHMENT FEE.—The biosimilar biologi-  
10          cal product establishment fee under subsection  
11          (a)(3) for a fiscal year shall be equal to the  
12          amount established under section 736(c)(4) for  
13          a prescription drug establishment for that fiscal  
14          year.

15          “(F) BIOSIMILAR BIOLOGICAL PRODUCT  
16          FEE.—The biosimilar biological product fee  
17          under subsection (a)(4) for a fiscal year shall be  
18          equal to the amount established under section  
19          736(c)(4) for a prescription drug product for  
20          that fiscal year.

21          “(2) LIMIT.—The total amount of fees charged  
22          for a fiscal year under this section may not exceed  
23          the total amount for such fiscal year of the costs of  
24          resources allocated for the process for the review of  
25          biosimilar biological product applications.



1       “(c) APPLICATION FEE WAIVER FOR SMALL BUSI-  
2   NESS.—

3               “(1) WAIVER OF APPLICATION FEE.—The Sec-  
4       retary shall grant to a person who is named in a bio-  
5       similar biological product application a waiver from  
6       the application fee assessed to that person under  
7       subsection (a)(2)(A) for the first biosimilar biologi-  
8       cal product application that a small business or its  
9       affiliate submits to the Secretary for review. After a  
10      small business or its affiliate is granted such a waiv-  
11      er, the small business or its affiliate shall pay—

12              “(A) application fees for all subsequent  
13      biosimilar biological product applications sub-  
14      mitted to the Secretary for review in the same  
15      manner as an entity that is not a small busi-  
16      ness; and

17              “(B) all supplement fees for all supple-  
18      ments to biosimilar biological product applica-  
19      tions submitted to the Secretary for review in  
20      the same manner as an entity that is not a  
21      small business.

22              “(2) CONSIDERATIONS.—In determining wheth-  
23      er to grant a waiver of a fee under paragraph (1),  
24      the Secretary shall consider only the circumstances

1 and assets of the applicant involved and any affiliate  
2 of the applicant.

3 “(3) SMALL BUSINESS DEFINED.—In this sub-  
4 section, the term ‘small business’ means an entity  
5 that has fewer than 500 employees, including em-  
6 ployees of affiliates, and does not have a drug prod-  
7 uct that has been approved under a human drug ap-  
8 plication (as defined in section 735) or a biosimilar  
9 biological product application (as defined in section  
10 744G(4)) and introduced or delivered for introduc-  
11 tion into interstate commerce.

12 “(d) EFFECT OF FAILURE TO PAY FEES.—A bio-  
13 similar biological product application or supplement sub-  
14 mitted by a person subject to fees under subsection (a)  
15 shall be considered incomplete and shall not be accepted  
16 for filing by the Secretary until all fees owed by such per-  
17 son have been paid.

18 “(e) CREDITING AND AVAILABILITY OF FEES.—

19 “(1) IN GENERAL.—Subject to paragraph (2),  
20 fees authorized under subsection (a) shall be col-  
21 lected and available for obligation only to the extent  
22 and in the amount provided in advance in appropria-  
23 tions Acts. Such fees are authorized to remain avail-  
24 able until expended. Such sums as may be necessary  
25 may be transferred from the Food and Drug Admin-

1       istration salaries and expenses appropriation account  
2       without fiscal year limitation to such appropriation  
3       account for salaries and expenses with such fiscal  
4       year limitation. The sums transferred shall be avail-  
5       able solely for the process for the review of bio-  
6       similar biological product applications.

7               “(2)   COLLECTIONS    AND    APPROPRIATION  
8       ACTS.—

9               “(A) IN GENERAL.—Subject to subpara-  
10       graphs (C) and (D), the fees authorized by this  
11       section shall be collected and available in each  
12       fiscal year in an amount not to exceed the  
13       amount specified in appropriation Acts, or oth-  
14       erwise made available for obligation for such  
15       fiscal year.

16              “(B) USE OF FEES AND LIMITATION.—  
17       The fees authorized by this section shall be  
18       available for a fiscal year beginning after fiscal  
19       year 2012 to defray the costs of the process for  
20       the review of biosimilar biological product appli-  
21       cations (including such costs for an additional  
22       number of full-time equivalent positions in the  
23       Department of Health and Human Services to  
24       be engaged in such process), only if the Sec-  
25       retary allocates for such purpose an amount for

1 such fiscal year (excluding amounts from fees  
2 collected under this section) no less than  
3 \$20,000,000, multiplied by the adjustment fac-  
4 tor applicable to the fiscal year involved.

5 “(C) FEE COLLECTION DURING FIRST  
6 PROGRAM YEAR.—Until the date of enactment  
7 of an Act making appropriations through Sep-  
8 tember 30, 2013, for the salaries and expenses  
9 account of the Food and Drug Administration,  
10 fees authorized by this section for fiscal year  
11 2013 may be collected and shall be credited to  
12 such account and remain available until ex-  
13 pended.

14 “(D) PROVISION FOR EARLY PAYMENTS IN  
15 SUBSEQUENT YEARS.—Payment of fees author-  
16 ized under this section for a fiscal year (after  
17 fiscal year 2013), prior to the due date for such  
18 fees, may be accepted by the Secretary in ac-  
19 cordance with authority provided in advance in  
20 a prior year appropriations Act.

21 “(3) AUTHORIZATION OF APPROPRIATIONS.—  
22 For each of fiscal years 2013 through 2017, there  
23 is authorized to be appropriated for fees under this  
24 section an amount equivalent to the total amount of  
25 fees assessed for such fiscal year under this section.

1       “(f) COLLECTION OF UNPAID FEES.—In any case  
2 where the Secretary does not receive payment of a fee as-  
3 sessed under subsection (a) within 30 days after it is due,  
4 such fee shall be treated as a claim of the United States  
5 Government subject to subchapter II of chapter 37 of title  
6 31, United States Code.

7       “(g) WRITTEN REQUESTS FOR WAIVERS AND RE-  
8 FUNDS.—To qualify for consideration for a waiver under  
9 subsection (c), or for a refund of any fee collected in ac-  
10 cordance with subsection (a)(2)(A), a person shall submit  
11 to the Secretary a written request for such waiver or re-  
12 fund not later than 180 days after such fee is due.

13       “(h) CONSTRUCTION.—This section may not be con-  
14 strued to require that the number of full-time equivalent  
15 positions in the Department of Health and Human Serv-  
16 ices, for officers, employers, and advisory committees not  
17 engaged in the process of the review of biosimilar biologi-  
18 cal product applications, be reduced to offset the number  
19 of officers, employees, and advisory committees so en-  
20 gaged.”.

21 **SEC. 403. REAUTHORIZATION; REPORTING REQUIREMENTS.**

22       Part 8 of subchapter C of chapter VII, as added by  
23 section 402 of this Act, is further amended by inserting  
24 after section 744H the following:

1 **“SEC. 744I. REAUTHORIZATION; REPORTING REQUIRE-**  
2 **MENTS.**

3       “(a) PERFORMANCE REPORT.—Beginning with fiscal  
4 year 2013, not later than 120 days after the end of each  
5 fiscal year for which fees are collected under this part,  
6 the Secretary shall prepare and submit to the Committee  
7 on Energy and Commerce of the House of Representatives  
8 and the Committee on Health, Education, Labor, and  
9 Pensions of the Senate a report concerning the progress  
10 of the Food and Drug Administration in achieving the  
11 goals identified in the letters described in section 401(b)  
12 of the Biosimilar User Fee Act of 2012 during such fiscal  
13 year and the future plans of the Food and Drug Adminis-  
14 tration for meeting such goals. The report for a fiscal year  
15 shall include information on all previous cohorts for which  
16 the Secretary has not given a complete response on all  
17 biosimilar biological product applications and supplements  
18 in the cohort.

19       “(b) FISCAL REPORT.—Not later than 120 days after  
20 the end of fiscal year 2013 and each subsequent fiscal year  
21 for which fees are collected under this part, the Secretary  
22 shall prepare and submit to the Committee on Energy and  
23 Commerce of the House of Representatives and the Com-  
24 mittee on Health, Education, Labor, and Pensions of the  
25 Senate a report on the implementation of the authority  
26 for such fees during such fiscal year and the use, by the

1 Food and Drug Administration, of the fees collected for  
2 such fiscal year.

3 “(c) PUBLIC AVAILABILITY.—The Secretary shall  
4 make the reports required under subsections (a) and (b)  
5 available to the public on the Internet Web site of the  
6 Food and Drug Administration.

7 “(d) STUDY.—

8 “(1) IN GENERAL.—The Secretary shall con-  
9 tract with an independent accounting or consulting  
10 firm to study the workload volume and full costs as-  
11 sociated with the process for the review of biosimilar  
12 biological product applications.

13 “(2) INTERIM RESULTS.—Not later than June  
14 1, 2015, the Secretary shall publish, for public com-  
15 ment, interim results of the study described under  
16 paragraph (1).

17 “(3) FINAL RESULTS.—Not later than Sep-  
18 tember 30, 2016, the Secretary shall publish, for  
19 public comment, the final results of the study de-  
20 scribed under paragraph (1).

21 “(e) REAUTHORIZATION.—

22 “(1) CONSULTATION.—In developing rec-  
23 ommendations to present to the Congress with re-  
24 spect to the goals described in subsection (a), and  
25 plans for meeting the goals, for the process for the

1 review of biosimilar biological product applications  
2 for the first 5 fiscal years after fiscal year 2017, and  
3 for the reauthorization of this part for such fiscal  
4 years, the Secretary shall consult with—

5 “(A) the Committee on Energy and Com-  
6 merce of the House of Representatives;

7 “(B) the Committee on Health, Education,  
8 Labor, and Pensions of the Senate;

9 “(C) scientific and academic experts;

10 “(D) health care professionals;

11 “(E) representatives of patient and con-  
12 sumer advocacy groups; and

13 “(F) the regulated industry.

14 “(2) PUBLIC REVIEW OF RECOMMENDA-  
15 TIONS.—After negotiations with the regulated indus-  
16 try, the Secretary shall—

17 “(A) present the recommendations devel-  
18 oped under paragraph (1) to the congressional  
19 committees specified in such paragraph;

20 “(B) publish such recommendations in the  
21 Federal Register;

22 “(C) provide for a period of 30 days for  
23 the public to provide written comments on such  
24 recommendations;



1           “(D) hold a meeting at which the public  
2           may present its views on such recommenda-  
3           tions; and

4           “(E) after consideration of such public  
5           views and comments, revise such recommenda-  
6           tions as necessary.

7           “(3) TRANSMITTAL OF RECOMMENDATIONS.—  
8           Not later than January 15, 2017, the Secretary  
9           shall transmit to the Congress the revised rec-  
10          ommendations under paragraph (2), a summary of  
11          the views and comments received under such para-  
12          graph, and any changes made to the recommenda-  
13          tions in response to such views and comments.”.

14   **SEC. 404. SUNSET DATES.**

15          (a) AUTHORIZATION.—Sections 744G and 744H, as  
16          added by section 402 of this Act, are repealed October  
17          1, 2017.

18          (b) REPORTING REQUIREMENTS.—Section 744I, as  
19          added by section 403 of this Act, is repealed January 31,  
20          2018.

21   **SEC. 405. EFFECTIVE DATE.**

22          (a) IN GENERAL.—Except as provided under sub-  
23          section (b), the amendments made by this title shall take  
24          effect on the later of—

25                  (1) October 1, 2012; or

1           (2) the date of the enactment of this title.

2           (b) **EXCEPTION.**—Fees under part 8 of subchapter  
3 C of chapter VII of the Federal Food, Drug, and Cosmetic  
4 Act, as added by this title, shall be assessed for all bio-  
5 similar biological product applications received on or after  
6 October 1, 2012, regardless of the date of the enactment  
7 of this title.

8 **SEC. 406. SAVINGS CLAUSE.**

9           Notwithstanding the amendments made by this title,  
10 part 2 of subchapter C of chapter VII of the Federal Food,  
11 Drug, and Cosmetic Act, as in effect on the day before  
12 the date of the enactment of this title, shall continue to  
13 be in effect with respect to human drug applications and  
14 supplements (as defined in such part as of such day) that  
15 were accepted by the Food and Drug Administration for  
16 filing on or after October 1, 2007, but before October 1,  
17 2012, with respect to assessing and collecting any fee re-  
18 quired by such part for a fiscal year prior to fiscal year  
19 2013.

20 **SEC. 407. CONFORMING AMENDMENT.**

21           Section 735(1)(B) (21 U.S.C. 379g(1)(B)) is amend-  
22 ed by striking “or (k)”.

1 **TITLE V—REAUTHORIZATION OF**  
 2 **BEST PHARMACEUTICALS**  
 3 **FOR CHILDREN ACT AND PE-**  
 4 **DIATRIC RESEARCH EQUITY**  
 5 **ACT**

6 **SEC. 501. PERMANENT EXTENSION OF BEST PHARMA-**  
 7 **CEUTICALS FOR CHILDREN ACT AND PEDI-**  
 8 **ATRIC RESEARCH EQUITY ACT.**

9 (a) PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.—  
 10 Section 409I(c) of the Public Health Service Act (42  
 11 U.S.C. 284m(c)) is amended—

12 (1) in subsection (c)(1)—

13 (A) in the matter preceding subparagraph  
 14 (A), by inserting “or section 351(m) of this  
 15 Act,” after “Cosmetic Act,”;

16 (B) in subparagraph (A)(i), by inserting  
 17 “or section 351(k) of this Act” after “Cosmetic  
 18 Act”; and

19 (C) by amending subparagraph (B) to read  
 20 as follows:

21 “(B)(i) there remains no patent listed pur-  
 22 suant to section 505(b)(1) of the Federal Food,  
 23 Drug, and Cosmetic Act; and

24 “(ii) every three-year and five-year period  
 25 referred to in subsection (c)(3)(E)(ii),

1 (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii),  
 2 (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of  
 3 the Federal Food, Drug and Cosmetic Act, or  
 4 applicable twelve-year period referred to in sec-  
 5 tion 351(k)(7) of this Act, and any seven-year  
 6 period referred to in section 527 of the Federal  
 7 Food, Drug, and Cosmetic Act, has ended for  
 8 at least one form of the drug; and”;

9 (2) in subsection (c)(2)—

10 (A) in the heading of paragraph (2), by  
 11 striking “FOR DRUGS LACKING EXCLUSIVITY”;

12 (B) by striking “under section 505 of the  
 13 Federal Food, Drug, and Cosmetic Act”; and

14 (C) by striking “505A of such Act” and  
 15 inserting “505A of the Federal Food, Drug,  
 16 and Cosmetic Act or section 351(m) of this  
 17 Act”; and

18 (3) in subsection (e)(1), by striking “to carry  
 19 out this section” and all that follows through the  
 20 end of paragraph (1) and inserting “\$25,000,000  
 21 for each of fiscal years 2013 through 2017.”.

22 (b) PEDIATRIC STUDIES OF DRUGS IN FFDCA.—  
 23 Section 505A (21 U.S.C. 355a) is amended—

24 (1) in subsection (d)(1)(A), by adding at the  
 25 end the following: “If a request under this subpara-

1 graph does not request studies in neonates, such re-  
 2 quest shall include a statement describing the ra-  
 3 tionale for not requesting studies in neonates.”;

4 (2) by amending subsection (h) to read as fol-  
 5 lows:

6 “(h) RELATIONSHIP TO PEDIATRIC RESEARCH RE-  
 7 QUIREMENTS.—Exclusivity under this section shall only be  
 8 granted for the completion of a study or studies that are  
 9 the subject of a written request and for which reports are  
 10 submitted and accepted in accordance with subsection  
 11 (d)(3). Written requests under this section may consist of  
 12 a study or studies required under section 505B.”;

13 (3) in subsection (k)(2), by striking “subsection  
 14 (f)(3)(F)” and inserting “subsection (f)(6)(F)”;

15 (4) in subsection (l)—

16 (A) in paragraph (1)—

17 (i) in the paragraph heading, by strik-  
 18 ing “YEAR ONE” and inserting “FIRST 18-  
 19 MONTH PERIOD”; and

20 (ii) by striking “one-year” and insert-  
 21 ing “18-month”;

22 (B) in paragraph (2)—

23 (i) in the paragraph heading, by strik-  
 24 ing “YEARS” and inserting “PERIODS”;  
 25 and

1 (ii) by striking “one-year period” and  
2 inserting “18-month period”;

3 (C) by redesignating paragraph (3) as  
4 paragraph (4); and

5 (D) by inserting after paragraph (2) the  
6 following:

7 “(3) PRESERVATION OF AUTHORITY.—Nothing  
8 in this subsection shall prohibit the Office of Pedi-  
9 atric Therapeutics from providing for the review of  
10 adverse event reports by the Pediatric Advisory  
11 Committee prior to the 18-month period referred to  
12 in paragraph (1), if such review is necessary to en-  
13 sure safe use of a drug in a pediatric population.”;

14 (5) in subsection (n)—

15 (A) in the subsection heading, by striking  
16 “COMPLETED” and inserting “SUBMITTED”;  
17 and

18 (B) in paragraph (1)—

19 (i) in the text preceding subparagraph  
20 (A), by striking “have not been completed”  
21 and inserting “have not been submitted by  
22 the date specified in the written request  
23 issued and agreed upon”; and

24 (ii) by revising subparagraphs (A) and  
25 (B) to read as follows:

1           “(A) For a drug for which there remains  
2           any listed patent or exclusivity protection eligi-  
3           ble for extension under subsection (b)(1) or  
4           (c)(1) of this section, or any exclusivity protec-  
5           tion eligible for extension under subsection  
6           (m)(2) or (m)(3) of section 351 of the Public  
7           Health Service Act, the Secretary shall make a  
8           determination regarding whether an assessment  
9           shall be required to be submitted under section  
10          505B(b).

11          “(B) For a drug that has no remaining  
12          listed patents or exclusivity protection eligible  
13          for extension under subsection (b)(1) or (c)(1)  
14          of this section, or any exclusivity protection eli-  
15          gible for extension under subsection (m)(2) or  
16          (m)(3) of section 351 of the Public Health  
17          Service Act, the Secretary shall refer the drug  
18          for inclusion on the list established under sec-  
19          tion 409I of the Public Health Service Act for  
20          the conduct of studies.”;

21          (6) in subsection (o)(2), by amending subpara-  
22          graph (B) to read as follows:

23                 “(B) a statement of any appropriate pedi-  
24                 atric contraindications, warnings, precautions,

1 or other information that the Secretary con-  
2 sider necessary to assure safe use.”; and

3 (7) by striking subsection (q) (relating to a sun-  
4 set).

5 (c) RESEARCH INTO PEDIATRIC USES FOR DRUGS  
6 AND BIOLOGICAL PROJECTS IN FFDCA.—Section 505B  
7 (21 U.S.C. 355c) is amended—

8 (1) in subsection (a)—

9 (A) in paragraph (1), in the matter before  
10 subparagraph (A), by inserting “for a drug”  
11 after “(or supplement to an application)”;

12 (B) in paragraph (3)—

13 (i) by redesignating subparagraph (B)  
14 as subparagraph (D); and

15 (ii) by inserting after subparagraph  
16 (A) the following:

17 “(B) DEFERRAL EXTENSION.—On the ini-  
18 tiative of the Secretary or at the request of the  
19 applicant, the Secretary may grant an extension  
20 of a deferral under subparagraph (A) if—

21 “(i) the Secretary finds that the cri-  
22 teria specified in subclause (II) or (III) of  
23 subparagraph (A)(i) continue to be met;  
24 and



1 “(ii) the applicant submits the mate-  
2 rials required under subparagraph (A)(ii).

3 “(C) CONSIDERATION DURING DEFERRAL  
4 PERIOD.—If the Secretary has under this para-  
5 graph deferred the date by which an assessment  
6 must be submitted, then until the date specified  
7 in the deferral under subparagraph (A) (includ-  
8 ing any extension of such date under subpara-  
9 graph (B))—

10 “(i) the assessment shall not be con-  
11 sidered late or delayed;

12 “(ii) the Secretary shall not classify  
13 the assessment as late or delayed in any  
14 report, database, or public posting.”; and

15 (iii) in subparagraph (D), as redesign-  
16 nated, by amending clause (ii) to read as  
17 follows:

18 “(ii) PUBLIC AVAILABILITY.—Not  
19 later than 60 days after the submission to  
20 the Secretary of the information submitted  
21 through the annual review under clause (i),  
22 the Secretary shall make available to the  
23 public in an easily accessible manner, in-  
24 cluding through the Web site of the Food  
25 and Drug Administration—

- 1 “(I) such information;
- 2 “(II) the name of the applicant
- 3 for the product subject to the assess-
- 4 ment;
- 5 “(III) the date on which the
- 6 product was approved; and
- 7 “(IV) the date of each deferral or
- 8 deferral extension under this para-
- 9 graph for the product.”; and
- 10 (C) in paragraph (4)(C)—
- 11 (i) in the first sentence, by inserting
- 12 “partial” before “waiver is granted”; and
- 13 (ii) in the second sentence, by striking
- 14 “either a full or partial waiver” and insert-
- 15 ing “a partial waiver”;
- 16 (2) in subsection (b)(1), by striking “After pro-
- 17 viding notice in the form of a letter (that, for a drug
- 18 approved under section 505, references a declined
- 19 written request under section 505A for a labeled in-
- 20 dication which written request is not referred under
- 21 section 505A(n)(1)(A) to the Foundation of the Na-
- 22 tional Institutes of Health for the pediatric studies),
- 23 the Secretary” and inserting “The Secretary”;
- 24 (3) by amending subsection (d) to read as fol-
- 25 lows:

1       “(d) FAILURE TO MEET REQUIREMENTS.—If a per-  
2 son fails to submit a required assessment described in sub-  
3 section (a)(2), fails to meet the applicable requirements  
4 in subsection (a)(3), or fails to submit a request for ap-  
5 proval of a pediatric formulation described in subsection  
6 (a) or (b), in accordance with applicable provisions of sub-  
7 sections (a) and (b)—

8               “(1)(A) the Secretary shall issue a letter to  
9 such person informing such person of such failure;

10              “(B) not later than 30 calendar days after the  
11 issuance of a letter under subparagraph (A), the  
12 person who receives such letter shall submit to the  
13 Secretary a written response to such letter; and

14              “(C) not later than 45 calendar days after the  
15 issuance of a letter under subparagraph (A), the  
16 Secretary shall make such letter, and any response  
17 to such letter under subparagraph (B), available to  
18 the public on the Web site of the Food and Drug  
19 Administration, with appropriate redactions made to  
20 protect trade secrets and confidential commercial in-  
21 formation, except that, if the Secretary determines  
22 that the letter under subparagraph (A) was issued  
23 in error, the requirements of this subparagraph shall  
24 not apply with respect to such letter; and

1 “(2)(A) the drug or biological product that is  
2 the subject of the required assessment, applicable re-  
3 quirements in subsection (a)(3), or required request  
4 for approval of a pediatric formulation may be con-  
5 sidered misbranded solely because of that failure and  
6 subject to relevant enforcement action (except that  
7 the drug or biological product shall not be subject to  
8 action under section 303); but

9 “(B) the failure to submit the required assess-  
10 ment, meet the applicable requirements in subsection  
11 (a)(3), or submit the required request for approval  
12 of a pediatric formulation shall not be the basis for  
13 a proceeding—

14 “(i) to withdraw approval for a drug under  
15 section 505(e); or

16 “(ii) to revoke the license for a biological  
17 product under section 351 of the Public Health  
18 Service Act.”;

19 (4) by amending subsection (e) to read as fol-  
20 lows:

21 “(e) INITIAL PEDIATRIC PLAN.—

22 “(1) IN GENERAL.—

23 “(A) SUBMISSION.—An applicant who is  
24 required to submit an assessment under sub-

1 section (a)(1) shall submit an initial pediatric  
2 plan.

3 “(B) TIMING.—An applicant shall submit  
4 the initial pediatric plan under paragraph (1)—

5 “(i) before the date on which the ap-  
6 plicant submits the assessments under sub-  
7 section (a)(2); and

8 “(ii) not later than—

9 “(I) 60 calendar days after the  
10 date of end-of-Phase 2 meeting (as  
11 such term is used in section 312.47 of  
12 title 21, Code of Federal Regulations,  
13 or successor regulations); or

14 “(II) such other time as may be  
15 agreed upon between the Secretary  
16 and the applicant.

17 Nothing in this section shall preclude the Sec-  
18 retary from accepting the submission of an ini-  
19 tial pediatric plan earlier than the date other-  
20 wise applicable under this subparagraph.

21 “(C) CONTENTS.—The initial pediatric  
22 plan shall include—

23 “(i) an outline of the pediatric studies  
24 that the applicant plans to conduct;

1 “(ii) any request for a deferral, partial  
2 waiver, or waiver under this section, along  
3 with supporting information; and

4 “(iii) other information the Secretary  
5 determines necessary, including any infor-  
6 mation specified in regulations under para-  
7 graph (5).

8 “(2) MEETING.—

9 “(A) IN GENERAL.—Subject to subpara-  
10 graph (B), not later than 90 calendar days  
11 after receiving an initial pediatric plan under  
12 paragraph (1), the Secretary shall meet with  
13 the applicant to discuss the plan.

14 “(B) WRITTEN RESPONSE.—If the Sec-  
15 retary determines that a written response to the  
16 initial pediatric plan is sufficient to commu-  
17 nicate comments on the initial pediatric plan,  
18 and that no meeting is necessary the Secretary  
19 shall, not later than 90 days after receiving an  
20 initial pediatric plan under paragraph (1)—

21 “(i) notify the applicant of such deter-  
22 mination; and

23 “(ii) provide to the applicant the Sec-  
24 retary’s written comments on the plan.

25 “(3) AGREED PEDIATRIC PLAN.—

1           “(A) SUBMISSION.—The applicant shall  
2           submit to the Secretary a document reflecting  
3           the agreement between the Secretary and the  
4           applicant on the initial pediatric plan (referred  
5           to in this subsection as an ‘agreed pediatric  
6           plan’).

7           “(B) CONFIRMATION.—Not later than 30  
8           days after receiving the agreed pediatric plan  
9           under subparagraph (A), the Secretary shall  
10          provide written confirmation to the applicant  
11          that such plan reflects the agreement of the  
12          Secretary.

13          “(C) DEFERRAL AND WAIVER.—If the  
14          agreed pediatric plan contains a request from  
15          the applicant for a deferral, partial waiver, or  
16          waiver under this section, the written confirma-  
17          tion under subparagraph (B) shall include a  
18          recommendation from the Secretary as to  
19          whether such request meets the standards  
20          under paragraphs (3) or (4) of subsection (a).

21          “(D) AMENDMENTS TO THE PLAN.—At  
22          the initiative of the Secretary or the applicant,  
23          the agreed pediatric plan may be amended at  
24          any time. The requirements of paragraph (2)  
25          shall apply to any such proposed amendment in

1 the same manner and to the same extent as  
2 such requirements apply to an initial pediatric  
3 plan under paragraph (1). The requirements of  
4 subparagraphs (A) through (C) of this para-  
5 graph shall apply to any agreement resulting  
6 from such proposed amendment in the same  
7 manner and to the same extent as such require-  
8 ments apply to an agreed pediatric plan.

9 “(4) INTERNAL COMMITTEE.—The Secretary  
10 shall consult the internal committee under section  
11 505C on the review of the initial pediatric plan,  
12 agreed pediatric plan, and any amendments to such  
13 plans.

14 “(5) MANDATORY RULEMAKING.—Not later  
15 than one year after the date of enactment of the  
16 Food and Drug Administration Reform Act of 2012,  
17 the Secretary shall promulgate proposed regulations  
18 and guidance to implement the provisions of this  
19 subsection.

20 “(6) EFFECTIVE DATE.—The provisions of this  
21 subsection shall take effect 180 calendar days after  
22 the date of enactment of the Food and Drug Admin-  
23 istration Reform Act of 2012, irrespective of wheth-  
24 er the Secretary has promulgated final regulations  
25 to carry out this subsection by such date.”;



1 (5) in subsection (f)—

2 (A) in the subsection heading, by inserting  
3 “DEFERRAL EXTENSIONS,” after “DEFER-  
4 RALS,”;

5 (B) in paragraph (4)—

6 (i) in the paragraph heading, by in-  
7 serting “DEFERRAL EXTENSIONS,” after  
8 “DEFERRALS,”; and

9 (ii) in the second sentence, by insert-  
10 ing “, deferral extensions,” after “defer-  
11 rals”; and

12 (C) in paragraph (6)(D)—

13 (i) by inserting “and deferral exten-  
14 sions” before “requested and granted”;  
15 and

16 (ii) by inserting “and deferral exten-  
17 sions” after “the reasons for such defer-  
18 rals”;

19 (6) in subsection (g)—

20 (A) in paragraph (1)(A), by striking “after  
21 the date of the submission of the application or  
22 supplement” and inserting “after the date of  
23 the submission of an application or supplement  
24 that receives a priority review or 330 days after  
25 the date of the submission of an application or

1 supplement that receives a standard review”;  
2 and

3 (B) in paragraph (2), by striking “the  
4 label of such product” and inserting “the label-  
5 ing of such product”;

6 (7) in subsection (h)(1)—

7 (A) by inserting “an application (or sup-  
8 plement to an application) that contains” after  
9 “date of submission of”; and

10 (B) by inserting “if the application (or  
11 supplement) receives a priority review, or not  
12 later than 330 days after the date of submis-  
13 sion of an application (or supplement to an ap-  
14 plication) that contains a pediatric assessment  
15 under this section, if the application (or supple-  
16 ment) receives a standard review,” after “under  
17 this section,”;

18 (8) in subsection (i)—

19 (A) in paragraph (1)—

20 (i) in the paragraph heading, by strik-  
21 ing “YEAR ONE” and inserting “FIRST 18-  
22 MONTH PERIOD”; and

23 (ii) by striking “one-year” and insert-  
24 ing “18-month”;

25 (B) in paragraph (2)—

1 (i) in the paragraph heading, by strik-  
 2 ing “YEARS” and inserting “PERIODS”;  
 3 and

4 (ii) by striking “one-year period” and  
 5 inserting “18-month period”;

6 (C) by redesignating paragraph (3) as  
 7 paragraph (4); and

8 (D) by inserting after paragraph (2) the  
 9 following:

10 “(3) PRESERVATION OF AUTHORITY.—Nothing  
 11 in this subsection shall prohibit the Office of Pedi-  
 12 atric Therapeutics from providing for the review of  
 13 adverse event reports by the Pediatric Advisory  
 14 Committee prior to the 18-month period referred to  
 15 in paragraph (1), if such review is necessary to en-  
 16 sure safe use of a drug in a pediatric population.”;

17 (9) by striking subsection (m) (relating to inte-  
 18 gration with other pediatric studies); and

19 (10) by redesignating subsection (n) as sub-  
 20 section (m).

21 (d) PEDIATRIC STUDIES OF BIOLOGICAL PRODUCTS  
 22 IN PHSA.—Section 351(m)(1) of the Public Health Serv-  
 23 ice Act (42 U.S.C. 262(m)(1)) is amended by striking “(f),  
 24 (i), (j), (k), (l), (p), and (q)” and inserting “(f), (h), (i),  
 25 (j), (k), (l), (n), and (p)”.

1 (e) APPLICATION; TRANSITION RULE.—

2 (1) APPLICATION.—Notwithstanding any provi-  
3 sion of section 505A and 505B of the Federal Food,  
4 Drug, and Cosmetic Act (21 U.S.C. 355a, 355c)  
5 stating that a provision applies beginning on the  
6 date of the enactment of the Best Pharmaceuticals  
7 for Children Act of 2007 or the date of the enact-  
8 ment of the Pediatric Research Equity Act of 2007,  
9 any amendment made by this Act to such a provi-  
10 sion applies beginning on the date of the enactment  
11 of this Act.

12 (2) TRANSITIONAL RULE FOR ADVERSE EVENT  
13 REPORTING.—With respect to a drug for which a la-  
14 beling change described under section 505A(l)(1) or  
15 505B(i)(1) of the Federal Food, Drug, and Cosmetic  
16 Act (21 U.S.C. 355a(l)(1); 355c(i)(1)) is approved  
17 or made, respectively, during the one-year period  
18 that ends on the day before the date of enactment  
19 of this Act, the Secretary shall apply section 505A(l)  
20 and section 505B(i), as applicable, to such drug, as  
21 such sections were in effect on such day.

22 (f) CONFORMING AMENDMENT.—Section  
23 499(c)(1)(C) of the Public Health Service Act (42 U.S.C.  
24 290b(c)(1)(C)) is amended by striking “for which the Sec-  
25 retary issues a certification in the affirmative under sec-

tion 505A(n)(1)(A) of the Federal Food, Drug, and Cosmetic Act”.

(g) PUBLIC MEETING ON PEDIATRIC CANCERS.—  
Not later than December 31, 2013, the Secretary of Health and Human Services shall hold a public meeting on the impact of sections 505A and 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a, 355c) on the development of new therapies for children with cancer.

**SEC. 502. FOOD AND DRUG ADMINISTRATION REPORT.**

(a) IN GENERAL.—Not later than four years after the date of enactment of this Act and every five years thereafter, the Secretary of Health and Human Services shall prepare and submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the Web site of the Food and Drug Administration, a report on the implementation of section 505A and 505B.

(b) CONTENTS.—The report described in paragraph (1) shall include—

(1) an assessment of the effectiveness of sections 505A and 505B in improving information about pediatric uses for approved drugs and bio-

1 logics, including the number and type of labeling  
2 changes made since the date of enactment of this  
3 Act;

4 (2) the number of waivers and partial waivers  
5 granted under section 505B since the date of enact-  
6 ment of this Act, and the reasons such waivers and  
7 partial waivers were granted;

8 (3) the number of deferrals and deferral exten-  
9 sions granted under section 505B since the date of  
10 enactment of this Act, and the reasons such defer-  
11 rals and deferral extensions were granted;

12 (4) the number of letters issued under section  
13 505B(d);

14 (5) an assessment of the timeliness and effec-  
15 tiveness of pediatric study planning since the date of  
16 enactment of this Act, including the number of pedi-  
17 atric plans not submitted in accordance with the re-  
18 quirements of section 505B(e) and any resulting  
19 rulemaking;

20 (6) the number of written requests issued, ac-  
21 cepted, and declined under section 505A since the  
22 date of enactment of this Act, and a listing of any  
23 important gaps in pediatric information as a result  
24 of such declined requests;

1           (7) a description and current status of referrals  
2       made under section 505A(n);

3           (8) an assessment of the effectiveness of study-  
4       ing drugs for rare diseases under 505A;

5           (9) an assessment of the effectiveness of study-  
6       ing drugs for children with cancer under 505A and  
7       505B, and any recommendations for modifications  
8       to the programs under such sections that would lead  
9       to new and better therapies for children with cancer;

10          (10) an assessment of the effectiveness of  
11       studying drugs in the neonate population under  
12       505A and 505B;

13          (11) an assessment of the effectiveness of  
14       studying biological products in pediatric populations  
15       under 505A and 505B;

16          (12) an assessment of the Secretary's efforts to  
17       address the suggestions and options described in the  
18       report required under 505A(p);

19          (13) any suggestions for modification to the  
20       programs that would improve pediatric drug re-  
21       search and increase pediatric labeling of drugs and  
22       biologics that the Secretary determines to be appro-  
23       priate.

24       (c) STAKEHOLDER COMMENT.—At least 180 days  
25       prior to the submission of the report required in para-

1 graph (1), the Secretary shall consult with representatives  
2 of patient groups, including pediatric patient groups, con-  
3 sumer groups, regulated industry, academia, and other in-  
4 terested parties to obtain any recommendations or infor-  
5 mation relevant to the study and report including sugges-  
6 tions for modifications that would improve pediatric drug  
7 research and pediatric labeling of drugs and biologics.

8 **SEC. 503. INTERNAL COMMITTEE FOR REVIEW OF PEDI-**  
9 **ATRIC PLANS, ASSESSMENTS, DEFERRALS,**  
10 **DEFERRAL EXTENSIONS, AND WAIVERS.**

11 Section 505C (21 U.S.C. 355d) is amended—

12 (1) in the section heading, by inserting “**DE-**  
13 **FERRAL EXTENSIONS,**” after “**DEFERRALS,**”;  
14 and

15 (2) by inserting “neonatology” after “pediatric  
16 ethics”.

17 **SEC. 504. STAFF OF OFFICE OF PEDIATRIC THERAPEUTICS.**

18 Section 6(c) of the Best Pharmaceuticals for Children  
19 Act (21 U.S.C. 393a(c)) is amended—

20 (1) in paragraph (1), by striking “and” at the  
21 end;

22 (2) by redesignating paragraph (2) as para-  
23 graph (4);

24 (3) by inserting after paragraph (1) the fol-  
25 lowing:



1           “(2) one or more additional individuals with ex-  
2       pertise in neonatology;

3           “(3) one or more additional individuals with ex-  
4       pertise in pediatric epidemiology; and”.

5       **SEC. 505. CONTINUATION OF OPERATION OF PEDIATRIC**  
6                               **ADVISORY COMMITTEE.**

7       Section 14(d) of the Best Pharmaceuticals for Chil-  
8       dren Act (42 U.S.C. 284m note) is amended by striking  
9       “during the five-year period beginning on the date of the  
10      enactment of the Best Pharmaceuticals for Children Act  
11      of 2007” and inserting “to carry out the advisory commit-  
12      tee’s responsibilities under sections 505A, 505B, and  
13      520(m) of the Federal Food, Drug, and Cosmetic Act (21  
14      U.S.C. 355a, 355c, and 360j(m))”.

15      **SEC. 506. PEDIATRIC SUBCOMMITTEE OF THE ONCOLOGIC**  
16                               **DRUGS ADVISORY COMMITTEE.**

17      Section 15(a) of the Best Pharmaceuticals for Chil-  
18      dren Act (Public Law 107–109), as amended by section  
19      502(e) of the Food and Drug Administration Amendments  
20      Act of 2007 (Public Law 110–85), is amended—

21           (1) in paragraph (1)(D), by striking “section  
22      505B(f)” and inserting “section 505C”; and

23           (2) in paragraph (3), by striking “during the  
24      five-year period beginning on the date of the enact-  
25      ment of the Best Pharmaceuticals for Children Act

1 of 2007” and inserting “to carry out the Sub-  
2 committee’s responsibilities under this section”.

3 **TITLE VI—FOOD AND DRUG AD-**  
4 **MINISTRATION ADMINISTRATIVE REFORMS**

6 **SEC. 601. PUBLIC PARTICIPATION IN ISSUANCE OF FDA**  
7 **GUIDANCE DOCUMENTS.**

8 Section 701(h)(1) (21 U.S.C. 371(h)(1)) is amended  
9 by striking subparagraph (C) and inserting the following:

10 “(C) For any guidance document that sets  
11 forth initial interpretations of a statute or regu-  
12 lation, sets forth changes in interpretation or  
13 policy that are of more than a minor nature, in-  
14 cludes complex scientific issues, or covers highly  
15 controversial issues—

16 “(i) the Secretary—

17 “(I) at least 30 days before  
18 issuance of a draft of such guidance  
19 document, shall publish notice in the  
20 Federal Register of the Secretary’s in-  
21 tent to prepare such guidance docu-  
22 ment; and

23 “(II) during preparation and be-  
24 fore issuance of such guidance docu-  
25 ment, may meet with interested stake-

1 holders, including industry, medical,  
2 and scientific experts and others, and  
3 solicit public comment;

4 “(ii) if the Secretary for good cause  
5 finds that, with respect to such guidance  
6 document, compliance with clause (i) is im-  
7 practicable, unnecessary, or contrary to the  
8 public interest—

9 “(I) the Secretary shall publish  
10 such finding and a brief statement of  
11 the reasons for such finding in the  
12 Federal Register;

13 “(II) clause (i) shall not apply  
14 with respect to such guidance docu-  
15 ment; and

16 “(III) during a 90-day period be-  
17 ginning not later than the date of  
18 issuance of the draft of such guidance  
19 document, the Secretary may meet  
20 with interested stakeholders, including  
21 industry, medical, and scientific ex-  
22 perts and others, and shall solicit pub-  
23 lic comment;

24 “(iii) beginning on the date of enact-  
25 ment of the Food and Drug Administra-

1           tion Reform Act of 2012, upon issuance of  
2           a draft guidance document under clause (i)  
3           or (ii), the Secretary shall—

4                   “(I) designate the document as  
5                   draft or final; and

6                   “(II) not later than 18 months  
7                   after the close of the comment period  
8                   for such guidance, issue a final  
9                   version of such guidance document in  
10                  accordance with clauses (i) and (ii);

11                  “(iv) the Secretary may extend the  
12                  deadline for issuing final guidance under  
13                  clause (iii)(II) by not more than 180 days  
14                  upon submission by the Secretary of a no-  
15                  tification of such extension in the Federal  
16                  Register;

17                  “(v) if the Secretary issues a draft  
18                  guidance document and fails to finalize the  
19                  draft by the deadline determined under  
20                  clause (iii)(II), as extended under clause  
21                  (iv), the Secretary shall, beginning on the  
22                  date of such deadline, treat the draft as  
23                  null and void; and

24                  “(vi) not less than every 5 years after  
25                  the issuance of a final guidance document

1 in accordance with clause (iii), the Sec-  
2 retary shall—

3 “(I) conduct a retrospective anal-  
4 ysis of such guidance document to en-  
5 sure it is not outmoded, ineffective,  
6 insufficient, or excessively burden-  
7 some; and

8 “(II) based on such analysis,  
9 modify, streamline, expand, or repeal  
10 the guidance document in accordance  
11 with what has been learned.

12 “(D) With respect to devices, a notice to  
13 industry guidance letter, a notice to industry  
14 advisory letter, and any similar notice that sets  
15 forth initial interpretations of a statute or regu-  
16 lation or sets forth changes in interpretation or  
17 policy shall be treated as a guidance document  
18 for purposes of subparagraph (C).

19 “(E) The following shall not be treated as  
20 a guidance document for purposes of subpara-  
21 graph (C):

22 “(i) Any document that does not set  
23 forth an initial interpretation or a reinter-  
24 pretation of a statute or regulation.

1                   “(ii) Any document that sets forth or  
2                   changes a policy relating to internal proce-  
3                   dures of the Food and Drug Administra-  
4                   tion.

5                   “(iii) Agency reports, general informa-  
6                   tion documents provided to consumers or  
7                   health professionals, speeches, journal arti-  
8                   cles and editorials, media interviews, press  
9                   materials, warning letters, memoranda of  
10                  understanding, or communications directed  
11                  to individual persons or firms.”.

12 **SEC. 602. CONFLICTS OF INTEREST.**

13           (a) IN GENERAL.—Section 712 (21 U.S.C. 379d–1)  
14 is amended—

15                   (1) by striking subsections (b) and (c) and in-  
16                   serting the following subsections:

17           “(b) RECRUITMENT FOR ADVISORY COMMITTEES.—

18                   “(1) IN GENERAL.—The Secretary shall—

19                           “(A) develop and implement strategies on  
20                           effective outreach to potential members of advi-  
21                           sory committees at universities, colleges, other  
22                           academic research centers, professional and  
23                           medical societies, and patient and consumer  
24                           groups;

1           “(B) seek input from professional medical  
2           and scientific societies to determine the most ef-  
3           fective informational and recruitment activities;

4           “(C) at least every 180 days, request refer-  
5           rals for potential members of advisory commit-  
6           tees from a variety of stakeholders, including—

7                   “(i) product developers, patient  
8                   groups, and disease advocacy organiza-  
9                   tions; and

10                   “(ii) relevant—

11                           “(I) professional societies;

12                           “(II) medical societies;

13                           “(III) academic organizations;

14                           and

15                           “(IV) governmental organiza-  
16                           tions; and

17           “(D) in carrying out subparagraphs (A)  
18           and (B), take into account the levels of activity  
19           (including the numbers of annual meetings) and  
20           the numbers of vacancies of the advisory com-  
21           mittees.

22           “(2) RECRUITMENT ACTIVITIES.—The recruit-  
23           ment activities under paragraph (1) may include—

1           “(A) advertising the process for becoming  
2           an advisory committee member at medical and  
3           scientific society conferences;

4           “(B) making widely available, including by  
5           using existing electronic communications chan-  
6           nels, the contact information for the Food and  
7           Drug Administration point of contact regarding  
8           advisory committee nominations; and

9           “(C) developing a method through which  
10          an entity receiving funding from the National  
11          Institutes of Health, the Agency for Healthcare  
12          Research and Quality, the Centers for Disease  
13          Control and Prevention, or the Veterans Health  
14          Administration can identify a person whom the  
15          Food and Drug Administration can contact re-  
16          garding the nomination of individuals to serve  
17          on advisory committees.

18          “(3) EXPERTISE.—In carrying out this sub-  
19          section, the Secretary shall seek to ensure that the  
20          Secretary has access to the most current expert ad-  
21          vice.

22          “(c) DISCLOSURE OF DETERMINATIONS AND CER-  
23          TIFICATIONS.—Notwithstanding section 107(a)(2) of the  
24          Ethics in Government Act of 1978, the following shall  
25          apply:



1           “(1) 15 OR MORE DAYS IN ADVANCE.—As soon  
2           as practicable, but (except as provided in paragraph  
3           (2)) not later than 15 days prior to a meeting of an  
4           advisory committee to which a written determination  
5           as referred to in section 208(b)(1) of title 18,  
6           United States Code, or a written certification as re-  
7           ferred to in section 208(b)(3) of such title, applies,  
8           the Secretary shall disclose (other than information  
9           exempted from disclosure under section 552 or sec-  
10          tion 552a of title 5, United States Code (popularly  
11          known as the Freedom of Information Act and the  
12          Privacy Act of 1974, respectively)) on the Internet  
13          Website of the Food and Drug Administration—

14                 “(A) the type, nature, and magnitude of  
15                 the financial interests of the advisory committee  
16                 member to which such determination or certifi-  
17                 cation applies; and

18                 “(B) the reasons of the Secretary for such  
19                 determination or certification, including, as ap-  
20                 propriate, the public health interest in having  
21                 the expertise of the member with respect to the  
22                 particular matter before the advisory com-  
23                 mittee.

24           “(2) LESS THAN 30 DAYS IN ADVANCE.—In the  
25          case of a financial interest that becomes known to

1 the Secretary less than 30 days prior to a meeting  
2 of an advisory committee to which a written deter-  
3 mination as referred to in section 208(b)(1) of title  
4 18, United States Code, or a written certification as  
5 referred to in section 208(b)(3) of such title applies,  
6 the Secretary shall disclose (other than information  
7 exempted from disclosure under section 552 or 552a  
8 of title 5, United States Code) on the Internet  
9 Website of the Food and Drug Administration, the  
10 information described in subparagraphs (A), (B),  
11 and (C) of paragraph (1) as soon as practicable  
12 after the Secretary makes such determination or cer-  
13 tification, but in no case later than the date of such  
14 meeting.”;

15 (2) in subsection (d), by striking “subsection  
16 (c)(3)” and inserting “subsection (c)”;

17 (3) by amending subsection (e) to read as fol-  
18 lows:

19 “(e) ANNUAL REPORT.—

20 “(1) IN GENERAL.—Not later than February 1  
21 of each year, the Secretary shall submit to the Com-  
22 mittee on Appropriations and the Committee on  
23 Health, Education, Labor, and Pensions of the Sen-  
24 ate, and the Committee on Appropriations and the

1 Committee on Energy and Commerce of the House  
2 of Representatives, a report that describes—

3 “(A) with respect to the fiscal year that  
4 ended on September 30 of the previous year,  
5 the number of persons nominated for participa-  
6 tion at meetings for each advisory committee,  
7 the number of persons so nominated, and will-  
8 ing to serve, the number of vacancies on each  
9 advisory committee, and the number of persons  
10 contacted for service as members on each advi-  
11 sory committee meeting for each advisory com-  
12 mittee who did not participate because of the  
13 potential for such participation to constitute a  
14 disqualifying financial interest under section  
15 208 of title 18, United States Code;

16 “(B) with respect to such year, the number  
17 of persons contacted for services as members  
18 for each advisory committee meeting for each  
19 advisory committee who did not participate be-  
20 cause of reasons other than the potential for  
21 such participation to constitute a disqualifying  
22 financial interest under section 208 of title 18,  
23 United States Code;

1           “(C) with respect to such year, the number  
2           of members attending meetings for each advisory  
3           committee; and

4           “(D) with respect to such year, the aggregate  
5           number of disclosures required under subsection  
6           (d) and the percentage of individuals to  
7           whom such disclosures did not apply who served  
8           on such committee.

9           “(2) PUBLIC AVAILABILITY.—Not later than 30  
10          days after submitting any report under paragraph  
11          (1) to the committees specified in such paragraph,  
12          the Secretary shall make each such report available  
13          to the public.”; and

14          (4) in subsection (f), by striking “shall review  
15          guidance” and all that follows through the end of  
16          the subsection and inserting the following: “shall—

17          “(1) review guidance of the Food and Drug Administration  
18          with respect to advisory committees regarding disclosure of conflicts of interest and the application  
19          of section 208 of title 18, United States  
20          Code; and

22          “(2) update such guidance as necessary to ensure  
23          that the Food and Drug Administration receives appropriate access to needed scientific exper-

1       tise, with due consideration of the requirements of  
2       such section 208.”.

3       (b) APPLICABILITY.—The amendments made by sub-  
4       section (a) apply beginning on October 1, 2012.

5       **SEC. 603. ELECTRONIC SUBMISSION OF APPLICATIONS.**

6       Subchapter D of chapter VII (21 U.S.C. 379k et  
7       seq.) is amended by inserting after section 745 the fol-  
8       lowing:

9       **“SEC. 745A. ELECTRONIC FORMAT FOR SUBMISSIONS.**

10       “(a) DRUGS AND BIOLOGICS.—

11               “(1) IN GENERAL.—Beginning no earlier than  
12       24 months after the issuance of a final guidance  
13       issued after public notice and opportunity for com-  
14       ment, submissions under subsection (b), (i), or (j) of  
15       section 505 of this Act or subsection (a) or (k) of  
16       section 351 of the Public Health Service Act shall  
17       be submitted in such electronic format as specified  
18       by the Secretary in such guidance.

19               “(2) GUIDANCE CONTENTS.—In the guidance  
20       under paragraph (1), the Secretary may—

21                       “(A) provide a timetable for establishment  
22       by the Secretary of further standards for elec-  
23       tronic submission as required by such para-  
24       graph; and

1           “(B) set forth criteria for waivers of and  
2           exemptions from the requirements of this sub-  
3           section.

4           “(3) EXCEPTION.—This subsection shall not  
5           apply to submissions described in section 561.

6           “(b) DEVICES.—

7           “(1) IN GENERAL.—Beginning after the  
8           issuance of final guidance implementing this para-  
9           graph, pre-submissions and submissions for devices  
10          under section 510(k), 513(f)(2)(A), 515(c), 515(d),  
11          515(f), 520(g), 520(m), or 564 of this Act or section  
12          351 of the Public Health Service Act, and any sup-  
13          plements to such pre-submissions or submissions,  
14          shall include an electronic copy of such pre-submis-  
15          sions or submissions.

16          “(2) GUIDANCE CONTENTS.—In the guidance  
17          under paragraph (1), the Secretary may—

18                 “(A) provide standards for the electronic  
19                 copy required under such paragraph; and

20                 “(B) set forth criteria for waivers of and  
21                 exemptions from the requirements of this sub-  
22                 section.”.

1 **SEC. 604. NOTIFICATION OF FDA INTENT TO REGULATE**  
2 **LABORATORY-DEVELOPED TESTS.**

3 The Food and Drug Administration may not issue  
4 any draft or final guidance on the regulation of laboratory-  
5 developed tests under the Federal Food, Drug, and Cos-  
6 metic Act (21 U.S.C. 301 et seq.) without, at least 60  
7 days prior to such issuance—

8 (1) notifying the Committee on Energy and  
9 Commerce of the House of Representatives and the  
10 Committee on Health, Education, Labor, and Pen-  
11 sions of the Senate of the Administration’s intent to  
12 take such action; and

13 (2) including in such notification the antici-  
14 pated details of such action.

15 **TITLE VII—MEDICAL DEVICE**  
16 **REGULATORY IMPROVEMENTS**  
17 **Subtitle A—Premarket**  
18 **Predictability**

19 **SEC. 701. INVESTIGATIONAL DEVICE EXEMPTIONS.**

20 Section 520(g) (21 U.S.C. 360j(g)) is amended—

21 (1) in paragraph (2)(B)(ii), by inserting “safety  
22 or effectiveness” before “data obtained”; and

23 (2) in paragraph (4), by adding at the end the  
24 following:

1 “(C) Consistent with paragraph (1), the Secretary  
2 shall not disapprove an application under this subsection  
3 because the Secretary determines that—

4 “(i) the investigation may not support a sub-  
5 stantial equivalence or de novo classification deter-  
6 mination or approval of the device;

7 “(ii) the investigation may not meet a require-  
8 ment, including a data requirement, relating to the  
9 approval or clearance of a device; or

10 “(iii) an additional or different investigation  
11 may be necessary to support clearance or approval  
12 of the device.”.

13 **SEC. 702. CLARIFICATION OF LEAST BURDENSOME STAND-**  
14 **ARD.**

15 (a) **PREMARKET APPROVAL.**—Section 513(a)(3)(D)  
16 (21 U.S.C. 360c(a)(3)(D)) is amended—

17 (1) by redesignating clause (iii) as clause (v);  
18 and

19 (2) by inserting after clause (ii) the following:

20 “(iii) For purposes of clause (ii), the  
21 term ‘necessary’ means the minimum re-  
22 quired information that would support a  
23 determination by the Secretary that an ap-  
24 plication provides reasonable assurance of  
25 the effectiveness of the device.



1                   “(iv) Nothing in this subparagraph  
2                   shall alter the criteria for evaluating an  
3                   application for premarket approval of a de-  
4                   vice.”.

5           (b) PREMARKET NOTIFICATION UNDER SECTION  
6 510(k).—Section 513(i)(1)(D) (21 U.S.C. 360e(i)(1)(D))  
7 is amended—

8                   (1) by striking “(D) Whenever” and inserting  
9                   “(D)(i) Whenever”; and

10                  (2) by adding at the end the following:

11                  “(ii) For purposes of clause (i), the term ‘necessary’  
12 means the minimum required information that would sup-  
13 port a determination of substantial equivalence between  
14 a new device and a predicate device.

15                  “(iii) Nothing in this subparagraph shall alter the  
16 standard for determining substantial equivalence between  
17 a new device and a predicate device.”.

18 **SEC. 703. AGENCY DOCUMENTATION AND REVIEW OF SIG-**  
19 **NIFICANT DECISIONS.**

20           Chapter V is amended by inserting after section 517  
21 (21 U.S.C. 360g) the following:

1 **“SEC. 517A. AGENCY DOCUMENTATION AND REVIEW OF**  
2 **SIGNIFICANT DECISIONS REGARDING DE-**  
3 **VICES.**

4 “(a) DOCUMENTATION OF RATIONALE FOR SIGNIFI-  
5 CANT DECISIONS.—

6 “(1) IN GENERAL.—The Secretary shall com-  
7 pletely document the scientific and regulatory ration-  
8 ale for any significant decision of the Center for De-  
9 vices and Radiological Health regarding submission  
10 or review of a report under section 510(k), an appli-  
11 cation under section 515, or an application for an  
12 exemption under section 520(g), including docu-  
13 mentation of significant controversies or differences  
14 of opinion and the resolution of such controversies  
15 or differences of opinion.

16 “(2) PROVISION OF DOCUMENTATION.—Upon  
17 request, the Secretary shall furnish such complete  
18 documentation to the person who is seeking to sub-  
19 mit, or who has submitted, such report or applica-  
20 tion.

21 “(b) REVIEW OF SIGNIFICANT DECISIONS.—

22 “(1) REQUEST FOR SUPERVISORY REVIEW OF  
23 SIGNIFICANT DECISION.—Any person may request a  
24 supervisory review of the significant decision de-  
25 scribed in subsection (a)(1). Such review may be  
26 conducted at the next supervisory level or higher

1       above the individual who made the significant deci-  
2       sion.

3               “(2) SUBMISSION OF REQUEST.—A person re-  
4       questing a supervisory review under paragraph (1)  
5       shall submit such request to the Secretary not later  
6       than 30 days after such decision and shall indicate  
7       in the request whether such person seeks an in-per-  
8       son meeting or a teleconference review.

9               “(3) TIMEFRAME.—

10              “(A) IN GENERAL.—Except as provided in  
11       subparagraph (B), the Secretary shall schedule  
12       an in-person or teleconference review, if so re-  
13       quested, not later than 30 days after such re-  
14       quest is made. The Secretary shall issue a deci-  
15       sion to the person requesting a review under  
16       this subsection not later than 45 days after the  
17       request is made under paragraph (1), or, in the  
18       case of a person who requests an in-person  
19       meeting or teleconference, 30 days after such  
20       meeting or teleconference.

21              “(B) EXCEPTION.—Subparagraph (A)  
22       shall not apply in cases that are referred to ex-  
23       perts outside of the Food and Drug Adminis-  
24       tration.”.

1 **SEC. 704. TRANSPARENCY IN CLEARANCE PROCESS.**

2 (a) PUBLICATION OF DETAILED DECISION SUM-  
3 MARIES.—Section 520(h) (21 U.S.C. 360j(h)) is amended  
4 by adding at the end the following:

5 “(5) Subject to subsection (c) and section 301(j), the  
6 Secretary shall regularly publish detailed decision sum-  
7 maries for each clearance of a device under section 510(k)  
8 requiring clinical data.”.

9 (b) APPLICATION.—The requirement of section  
10 520(h)(5) of the Federal Food, Drug, and Cosmetic Act,  
11 as added by subsection (a), applies only with respect to  
12 clearance of a device occurring after the date of the enact-  
13 ment of this Act.

14 **SEC. 705. DEVICE MODIFICATIONS REQUIRING PREMARKET**  
15 **NOTIFICATION PRIOR TO MARKETING.**

16 Section 510(n) (21 U.S.C. 360(n)) is amended by—

17 (1) striking “(n) The Secretary” and inserting  
18 “(n)(1) The Secretary”; and

19 (2) by adding at the end the following:

20 “(2)(A) Not later than 18 months after the en-  
21 actment of this paragraph, the Secretary shall sub-  
22 mit to the Committee on Energy and Commerce of  
23 the House of Representatives and the Committee on  
24 Health, Education, Labor, and Pensions of the Sen-  
25 ate a report regarding when a premarket notification  
26 under subsection (k) should be submitted for a

1 modification or change to a legally marketed device.  
2 The report shall include the Secretary's interpreta-  
3 tion of the following terms: 'could significantly affect  
4 the safety or effectiveness of the device', 'a signifi-  
5 cant change or modification in design, material,  
6 chemical composition, energy source, or manufac-  
7 turing process,', and 'major change or modification  
8 in the intended use of the device'. The report also  
9 shall discuss possible processes for industry to use to  
10 determine whether a new submission under sub-  
11 section (k) is required and shall analyze how to le-  
12 verage existing quality system requirements to re-  
13 duce premarket burden, facilitate continual device  
14 improvement. and provide reasonable assurance of  
15 safety and effectiveness of modified devices. In de-  
16 veloping such report, the Secretary shall consider the  
17 input of interested stakeholders.

18 “(B) The Secretary shall withdraw the Food  
19 and Drug Administration draft guidance entitled  
20 ‘Guidance for Industry and FDA Staff—510(k) De-  
21 vice Modifications: Deciding When to Submit a  
22 510(k) for a Change to an Existing Device’, dated  
23 July 27, 2011, and shall not use this draft guidance  
24 as part of, or for the basis of, any premarket review

1 or any compliance or enforcement decisions or ac-  
2 tions. The Secretary shall not issue—

3 “(i) any draft guidance or proposed regula-  
4 tion that addresses when to submit a premarket  
5 notification submission for changes and modi-  
6 fications made to a manufacturer’s previously  
7 cleared device before the receipt by the Com-  
8 mittee on Energy and Commerce of the House  
9 of Representatives and the Committee on  
10 Health, Education, Labor, and Pensions of the  
11 Senate of the report required in subparagraph  
12 (A); and

13 “(ii) any final guidance or regulation on  
14 that topic for one year after date of receipt of  
15 such report by the Committee on Energy and  
16 Commerce of the House of Representatives and  
17 the Committee on Health, Education, Labor,  
18 and Pensions of the Senate.

19 “(C) The Food and Drug Administration guid-  
20 ance entitled ‘Deciding When to Submit a 510(k) for  
21 a Change to an Existing Device’, dated January 10,  
22 1997, shall be in effect until the subsequent issuance  
23 of guidance or promulgation, if appropriate, of a  
24 regulation described in subparagraph (B), and the  
25 Secretary shall interpret such guidance in a manner

1 that is consistent with the manner in which the Sec-  
2 retary has interpreted such guidance since 1997.”.

3 **Subtitle B—Patients Come First**

4 **SEC. 711. ESTABLISHMENT OF SCHEDULE AND PROMULGA-**  
5 **TION OF REGULATION.**

6 (a) ESTABLISHMENT OF SCHEDULE.—Not later than  
7 90 days after the date of enactment of this Act, the Sec-  
8 retary of Health and Human Services shall establish the  
9 schedule referred to in section 515(i)(3) of the Federal  
10 Food, Drug, and Cosmetic Act (21 U.S.C. 360e(i)(3)).

11 (b) REGULATION.—Not later than one year after the  
12 date that the schedule is established under such section  
13 515(i)(3) (as required by subsection (a)) the Secretary  
14 shall issue a final regulation under section 515(b) of such  
15 Act for each device that the Secretary requires to remain  
16 in class III through a determination under section  
17 515(i)(2) of such Act.

18 **SEC. 712. PROGRAM TO IMPROVE THE DEVICE RECALL SYS-**  
19 **TEM.**

20 Chapter V is amended by inserting after section 518  
21 (21 U.S.C. 360h) the following:

22 **“SEC. 518A. PROGRAM TO IMPROVE THE DEVICE RECALL**  
23 **SYSTEM.**

24 “(a) IN GENERAL.—The Secretary shall—

1           “(1) establish a program to routinely and sys-  
2           tematically assess information relating to device re-  
3           calls and use such information to proactively identify  
4           strategies for mitigating health risks presented by  
5           defective or unsafe devices;

6           “(2) clarify procedures for conducting device re-  
7           call audit checks to improve the ability of investiga-  
8           tors to perform those checks in a consistent manner;

9           “(3) develop detailed criteria for assessing  
10          whether a person performing a device recall has per-  
11          formed an effective correction or action plan for the  
12          recall; and

13          “(4) document the basis for each termination  
14          by the Food and Drug Administration of a device re-  
15          call.

16          “(b) ASSESSMENT CONTENT.—The program estab-  
17          lished under subsection (a)(1) shall, at a minimum, iden-  
18          tify—

19               “(1) trends in the number and types of device  
20               recalls;

21               “(2) devices that are most frequently the sub-  
22               ject of a recall; and

23               “(3) underlying causes of device recalls.

24          “(c) DEFINITION.—In this section, the term ‘recall’  
25          means—



1 “(1) the removal from the market of a device  
 2 pursuant to an order of the Secretary under sub-  
 3 section (b) or (e) of section 518; or

4 “(2) the correction or removal from the market  
 5 of a device at the initiative of the manufacturer or  
 6 importer of the device that is required to be reported  
 7 to the Secretary under section 519(g).”.

## 8 **Subtitle C—Novel Device** 9 **Regulatory Relief**

### 10 **SEC. 721. MODIFICATION OF DE NOVO APPLICATION PROC-** 11 **ESS.**

12 (a) IN GENERAL.—Section 513(f)(2) (21 U.S.C.  
 13 360c(f)(2)) is amended—

14 (1) by inserting “(i)” after “(2)(A)”;

15 (2) in subparagraph (A)(i), as so designated by  
 16 paragraph (1), by striking “under the criteria set  
 17 forth” and all that follows through the end of sub-  
 18 paragraph (A) and inserting a period;

19 (3) by adding at the end of subparagraph (A)  
 20 the following:

21 “(ii) In lieu of submitting a report under section  
 22 510(k) and submitting a request for classification under  
 23 clause (i) for a device, if a person determines there is no  
 24 legally marketed device upon which to base a determina-  
 25 tion of substantial equivalence (as defined in subsection

1 (i)), a person may submit a request under this clause for  
2 the Secretary to classify the device.

3 “(iii) Upon receipt of a request under clause (i) or  
4 (ii), the Secretary shall classify the device subject to the  
5 request under the criteria set forth in subparagraphs (A)  
6 through (C) of subsection (a)(1) within 120 days.

7 “(iv) Notwithstanding clause (iii), the Secretary may  
8 decline to undertake a classification of a device pursuant  
9 to a request under clause (ii) if the Secretary—

10 “(I) identifies a legally marketed device that  
11 would permit a substantial equivalence determina-  
12 tion under paragraph (1) for the device; or

13 “(II) determines that the device submitted is  
14 not of low-moderate risk or special controls to miti-  
15 gate the risks cannot be developed for the device.

16 “(v) The person submitting the request for classifica-  
17 tion under this subparagraph may recommend to the Sec-  
18 retary a classification for the device and shall, if recom-  
19 mending classification in class II, include in the request  
20 an initial draft proposal for applicable special controls, as  
21 described in subsection (a)(1)(B), that are necessary, in  
22 conjunction with general controls, to provide reasonable  
23 assurance of safety and effectiveness and a description of  
24 how the special controls provide such assurance. Any such  
25 request shall describe the device and provide detailed in-

1 formation and reasons for the recommended classifica-  
 2 tion.”; and

3 (4) in subparagraph (B), by striking “Not later  
 4 than 60 days after the date of the submission of the  
 5 request under subparagraph (A), the Secretary” and  
 6 inserting “The Secretary”.

7 (b) CONFORMING AMENDMENTS.—Section 513(f) of  
 8 such Act (21 U.S.C. 360c(f)) is amended in paragraph  
 9 (1)—

10 (1) in subparagraph (A), by striking “, or” at  
 11 the end and inserting a semicolon;

12 (2) in subparagraph (B), by striking the period  
 13 and inserting “; or”; and

14 (3) by inserting after subparagraph (B) the fol-  
 15 lowing:

16 “(C) the device is classified pursuant to a  
 17 request submitted under paragraph (2).”.

## 18 **Subtitle D—Keeping America Com-** 19 **petitive Through Harmonization**

### 20 **SEC. 731. HARMONIZATION OF DEVICE PREMARKET RE-** 21 **VIEW, INSPECTION, AND LABELING SYMBOLS;** 22 **REPORT.**

23 (a) IN GENERAL.—Paragraph (4) of section 803(c)  
 24 (21 U.S.C. 383(c)) is amended to read as follows:

1       “(4) With respect to devices, the Secretary may,  
2 when appropriate, enter into arrangements with nations  
3 regarding methods and approaches to harmonizing regu-  
4 latory requirements for activities, including inspections  
5 and common international labeling symbols”.

6       (b) REPORT.—Not later than 3 years after the date  
7 of enactment of this Act, the Secretary of Health and  
8 Human Services shall submit to the Committee on Health,  
9 Education, Labor, and Pensions of the Senate and the  
10 Committee on Energy and Commerce of the House of  
11 Representatives a report on the Food and Drug Adminis-  
12 tration’s harmonization activities, itemizing methods and  
13 approaches that have been harmonized pursuant to section  
14 803(c)(4) of the Federal Food, Drug, and Cosmetic Act,  
15 as amended by subsection (a).

16 **SEC. 732. PARTICIPATION IN INTERNATIONAL FORA.**

17       Paragraph (3) of section 803(c) (21 U.S.C. 383(c))  
18 is amended—

19               (1) by striking “(3)” and inserting “(3)(A)”;  
20       and

21               (2) by adding at the end the following:

22       “(B) In carrying out subparagraph (A), the Secretary  
23 may participate in appropriate fora, including the Inter-  
24 national Medical Device Regulators Forum, and may—

1 “(i) provide guidance to such fora on strategies,  
 2 policies, directions, membership, and other activities  
 3 of a forum as appropriate;

4 “(ii) to the extent appropriate, solicit, review,  
 5 and consider comments from industry, academia,  
 6 health care professionals, and patient groups regard-  
 7 ing the activities of such fora; and

8 “(iii) to the extent appropriate, inform the pub-  
 9 lic of the Secretary’s activities within such fora, and  
 10 share with the public any documentation relating to  
 11 a forum’s strategies, policies, and other activities of  
 12 such fora.”.

## 13 **Subtitle E—FDA Renewing Effi-** 14 **ciency From Outside Reviewer** 15 **Management**

### 16 **SEC. 741. REAUTHORIZATION OF THIRD PARTY REVIEW.**

17 (a) PERIODIC REACCREDITATION.—Section  
 18 523(b)(2) (21 U.S.C. 360m(b)(2)) is amended by adding  
 19 at the end of the following:

20 “(E) PERIODIC REACCREDITATION.—

21 “(i) PERIOD.—Subject to suspension  
 22 or withdrawal under subparagraph (B),  
 23 any accreditation under this section shall  
 24 be valid for a period of 3 years after its  
 25 issuance.

1           “(ii) RESPONSE TO REACCREDITATION  
2           REQUEST.—Upon the submission of a re-  
3           quest by an accredited person for re-  
4           accreditation under this section, the Sec-  
5           retary shall approve or deny such request  
6           not later than 60 days after receipt of the  
7           request.

8           “(iii) CRITERIA.—Not later than 120  
9           days after the date of the enactment of  
10          this subparagraph, the Secretary shall es-  
11          tablish and publish in the Federal Register  
12          criteria to reaccredit or deny reaccredita-  
13          tion to persons under this section. The re-  
14          accreditation of persons under this section  
15          shall specify the particular activities under  
16          subsection (a), and the devices, for which  
17          such persons are reaccredited.”.

18          (b) DURATION OF AUTHORITY.—Section 523(c) (21  
19          U.S.C. 360m(c)) is amended by striking “October 1,  
20          2012” and inserting “October 1, 2017”.

21          **SEC. 742. REAUTHORIZATION OF THIRD PARTY INSPEC-**  
22          **TION.**

23          Section 704(g)(11) (21 U.S.C. 374(g)(11)) is amend-  
24          ed by striking “October 1, 2012” and inserting “October  
25          1, 2017”.

**Subtitle F—Humanitarian Device  
Reform**

**SEC. 751. EXPANDED ACCESS TO HUMANITARIAN USE DE-  
VICES.**

(a) IN GENERAL.—Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (6)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i),  
by striking “subparagraph (D)” and in-  
serting “subparagraph (C)”;

(ii) by striking clause (i) and inserting  
the following:

“(i) The device with respect to which the ex-  
emption is granted—

“(I) is intended for the treatment or diag-  
nosis of a disease or condition that occurs in  
pediatric patients or in a pediatric subpopula-  
tion, and such device is labeled for use in pedi-  
atric patients or in a pediatric subpopulation in  
which the disease or condition occurs; or

“(II) is intended for the treatment or diag-  
nosis of a disease or condition that does not  
occur in pediatric patients or that occurs in pe-  
diatric patients in such numbers that the devel-

1           opment of the device for such patients is impos-  
2           sible, highly impracticable, or unsafe.”;

3                   (iii) by striking clause (ii) and insert-  
4           ing the following:

5           “(ii) During any calendar year, the number of  
6           such devices distributed during that year under each  
7           exemption granted under this subsection does not  
8           exceed the number of such devices needed to treat,  
9           diagnose, or cure a population of 4,000 individuals  
10          in the United States (referred to in this paragraph  
11          as the ‘annual distribution number’).”; and

12                   (iv) in clause (iv), by striking “2012”  
13          and inserting “2017”;

14                   (B) by striking subparagraph (C);

15                   (C) by redesignating subparagraphs (D)  
16          and (E) as subparagraphs (C) and (D), respec-  
17          tively; and

18                   (D) in subparagraph (C), as so redesign-  
19          ated, by striking “and modified under sub-  
20          paragraph (C), if applicable,”;

21                   (2) in paragraph (7), by striking “regarding a  
22          device” and inserting “regarding a device described  
23          in paragraph (6)(A)(i)(I)”; and



1           (3) in paragraph (8), by striking “of all devices  
2       described in paragraph (6)” and inserting “of all de-  
3       vices described in paragraph (6)(A)(i)(I)”.

4       (b) APPLICABILITY TO EXISTING DEVICES.—A spon-  
5       sor of a device for which an exemption was approved under  
6       paragraph (2) of section 520(m) of the Federal Food,  
7       Drug, and Cosmetic Act (21 U.S.C. 360j(m)) before the  
8       date of enactment of this Act may seek a determination  
9       under subclause (I) or (II) of paragraph (6)(A)(i) of such  
10      section 520(m) (as amended by subsection (a)). If the Sec-  
11      retary determines that such subclause (I) or (II) applies  
12      with respect to a device, then clauses (ii), (iii), and (iv)  
13      of subparagraph (A) and subparagraphs (B), (C), and (D)  
14      of paragraph (6) of such section 520(m) shall apply to  
15      such device.

16      (c) REPORT.—Not later than January 1, 2017, the  
17      Comptroller General of the United States shall submit to  
18      Congress a report that evaluates and describes—

19           (1) the effectiveness of the amendments made  
20       by subsection (a) in stimulating innovation with re-  
21       spect to medical devices, including any favorable or  
22       adverse impact on pediatric device development;

23           (2) the impact of such amendments on pediatric  
24       device approvals for devices that received a humani-  
25       tarian use designation under section 520(m) of the

1 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
2 360j(m)) prior to the date of enactment of this Act;

3 (3) the status of public and private insurance  
4 coverage of devices granted an exemption under  
5 paragraph (2) of such section 520(m) and costs to  
6 patients of such devices;

7 (4) the impact that paragraph (4) of such sec-  
8 tion 520(m) has had on access to and insurance cov-  
9 erage of devices granted an exemption under para-  
10 graph (2) of such section 520(m); and

11 (5) the effect of the amendments made by sub-  
12 section (a) on patients described in such section  
13 520(m).

## 14 **Subtitle G—Records and Reports** 15 **on Devices**

### 16 **SEC. 761. UNIQUE DEVICE IDENTIFICATION SYSTEM REGU-** 17 **LATIONS.**

18 Not later than 120 days after the date of enactment  
19 of this Act, the Secretary of Health and Human Services  
20 shall promulgate the regulations required by section  
21 519(f) of the Federal Food, Drug, and Cosmetic Act (21  
22 U.S.C. 360i(f)).

### 23 **SEC. 762. EFFECTIVE DEVICE SENTINEL PROGRAM.**

24 (a) INCLUSION OF DEVICES IN POSTMARKET RISK  
25 IDENTIFICATION AND ANALYSIS SYSTEM.—Section 519

1 (21 U.S.C. 360i) is amended by adding at the end the  
2 following:

3 “(h) INCLUSION OF DEVICES IN POSTMARKET RISK  
4 IDENTIFICATION AND ANALYSIS SYSTEM.—

5 “(1) IN GENERAL.—The Secretary shall amend  
6 the procedures established and maintained under  
7 clauses (i), (ii), (iii), and (v) of section 505(k)(3)(C)  
8 in order to expand the postmarket risk identification  
9 and analysis system established under such section  
10 to include and apply to devices.

11 “(2) DATA.—In expanding the system as de-  
12 scribed in paragraph (1), the Secretary shall use rel-  
13 evant data with respect to devices cleared under sec-  
14 tion 510(k) or approved under section 515, which  
15 may include claims data, patient survey data, and  
16 standardized analytic files that allow for the pooling  
17 and analysis of data from disparate data environ-  
18 ments.

19 “(3) STAKEHOLDER INPUT.—To help ensure ef-  
20 fective implementation of the system as described in  
21 paragraph (1) with respect to devices, the Secretary  
22 shall engage outside stakeholders in development of  
23 the system, and gather information from outside  
24 stakeholders regarding the content of an effective  
25 sentinel program, through a public hearing, advisory

committee meeting, maintenance of a public docket,  
or other similar public measures.

“(4) VOLUNTARY SURVEYS.—Chapter 35 of  
title 44, United States Code, shall not apply to the  
collection of voluntary information from health care  
providers, such as voluntary surveys or question-  
naires, initiated by the Secretary for purposes of  
postmarket risk identification, mitigation, and anal-  
ysis for devices.”.

(b) AMENDMENTS TO POSTMARKET RISK IDENTI-  
FICATION AND ANALYSIS SYSTEM.—Section  
505(k)(3)(C)(i) (21 U.S.C. 355(k)(3)(C)(i)) is amended—

(1) by striking subclause (II);

(2) by redesignating subclauses (III) through  
(VI) as subclauses (II) through (V), respectively;  
and

(3) in item (bb) of subclause (II), as so redesign-  
ated, by striking “pharmaceutical purchase data  
and health insurance claims data” and inserting  
“medical device utilization data, health insurance  
claims data, and procedure and device registries”.

## **Subtitle H—Miscellaneous**

### **SEC. 771. CUSTOM DEVICES.**

Section 520(b) (21 U.S.C. 360j) is amended to read  
as follows:

1 “(b) CUSTOM DEVICES.—

2 “(1) IN GENERAL.—The requirements of sec-  
3 tions 514 and 515 shall not apply to a device that—

4 “(A) is created or modified in order to  
5 comply with the order of an individual physician  
6 or dentist (or any other specially qualified per-  
7 son designated under regulations promulgated  
8 by the Secretary after an opportunity for an  
9 oral hearing);

10 “(B) in order to comply with an order de-  
11 scribed in subparagraph (A), necessarily devi-  
12 ates from an otherwise applicable performance  
13 standard under section 514 or requirement  
14 under section 515;

15 “(C) is not generally available in the  
16 United States in finished form through labeling  
17 or advertising by the manufacturer, importer,  
18 or distributor for commercial distribution;

19 “(D) is designed to treat a unique pathol-  
20 ogy or physiological condition that no other de-  
21 vice is domestically available to treat;

22 “(E)(i) is intended to meet the special  
23 needs of such physician or dentist (or other spe-  
24 cially qualified person so designated) in the  
25 course of the professional practice of such phy-

sician or dentist (or other specially qualified person so designated); or

“(ii) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated);

“(F) is assembled from components or manufactured and finished on a case-by-case basis to accommodate the unique needs of individuals described in clause (i) or (ii) of subparagraph (E); and

“(G) may have common, standardized design characteristics, chemical and material compositions, and manufacturing processes as commercially distributed devices.

“(2) LIMITATIONS.—Paragraph (1) shall apply to a device only if—

“(A) such device is for the purpose of treating a sufficiently rare condition, such that conducting clinical investigations on such device would be impractical; and

“(B) production of such device under paragraph (1) is limited to no more than 5 units per year of a particular device type, provided that

1           such replication otherwise complies with this  
2           section.

3           “(3) GUIDANCE.—Not later than 2 years after  
4           the date of enactment of this section, the Secretary  
5           shall issue final guidance on replication of multiple  
6           devices described in paragraph (2)(B).

7           “(4) NOTIFICATION TO THE SECRETARY.—The  
8           manufacturer of such device created or modified as  
9           described in paragraph (1) shall notify the Secretary  
10          on an annual basis, in a manner prescribed by the  
11          Secretary, of the manufacture of such device.”.

12 **SEC. 772. PEDIATRIC DEVICE REAUTHORIZATION.**

13          (a) FINAL RULE RELATING TO TRACKING OF PEDI-  
14          ATRIC USES OF DEVICES.—The Secretary of Health and  
15          Human Services shall issue—

16               (1) a proposed rule implementing section  
17               515A(a)(2) of the Federal Food, Drug and Cosmetic  
18               Act (21 U.S.C. 360e–1(a)(2)) not later than Decem-  
19               ber 31, 2012; and

20               (2) a final rule implementing such section not  
21               later than December 31, 2013.

22          (b) DEMONSTRATION GRANTS TO IMPROVE PEDI-  
23          ATRIC DEVICE AVAILABILITY.—Section 305(e) of the Pe-  
24          diatric Medical Device Safety and Improvement Act of  
25          2007 (Title III of Public Law 110–85) is amended by

1 striking “2008 through 2012” and inserting “2013  
2 through 2017”.

3 **SEC. 773. REPORT ON REGULATION OF HEALTH INFORMA-**  
4 **TION TECHNOLOGY.**

5 (a) REPORT.—Not later than 18 months after the  
6 date of the enactment of this Act, the Secretary of Health  
7 and Human Services, in consultation with the Commis-  
8 sioner of Food and Drugs, the National Coordinator for  
9 Health Information Technology, and the Chairman of the  
10 Federal Communications Commission, shall submit to the  
11 Committee on Energy and Commerce of the House of  
12 Representatives and the appropriate committees of the  
13 Senate a report that contains—

14 (1) a strategy for coordinating the regulation of  
15 health information technology in order to avoid regu-  
16 latory duplication; and

17 (2) recommendations on an appropriate regu-  
18 latory framework for health information technology,  
19 including a risk-based framework.

20 (b) DEFINITION.—In this section, the terms “health  
21 information technology” has the meaning given such term  
22 in section 3000(5) of the Public Health Service Act and  
23 includes technologies such as electronic health records,  
24 personal health records, mobile medical applications, com-



1 puterized health care provider order entry systems, and  
2 clinical decision support.

## 3 **TITLE VIII—DRUG REGULATORY** 4 **IMPROVEMENTS**

### 5 **Subtitle A—Drug Supply Chain**

#### 6 **SEC. 801. REGISTRATION OF PRODUCERS OF DRUGS.**

7 (a) TIMING.—Section 510 (21 U.S.C. 360) is amend-  
8 ed—

9 (1) in subsection (b)(1), by striking “On or be-  
10 fore” and inserting “During the period beginning on  
11 October 1 and ending on”; and

12 (2) in subsection (i)(1)(B)(i), by striking “on or  
13 before” and inserting “during the period beginning  
14 on October 1 and ending on”.

15 (b) ESTABLISHMENTS NOT DULY REGISTERED; MIS-  
16 BRANDING.—Section 502(o) (21 U.S.C. 352(o)) is amend-  
17 ed by striking “in any State”.

#### 18 **SEC. 802. INSPECTION OF DRUGS.**

19 Subsection (h) of section 510 (21 U.S.C. 360) is  
20 amended—

21 (1) by striking “(h)” and inserting “(h)(1)”;

22 (2) by inserting “with respect to the manufac-  
23 ture, preparation, propagation, compounding, or  
24 processing of a device” after “registered with the  
25 Secretary pursuant to this section”;

1 (3) by striking “of a drug or drugs or”; and

2 (4) by adding at the end the following:

3 “(2) INSPECTIONS WITH RESPECT TO DRUG ESTAB-  
4 LISHMENTS.—With respect to the manufacture, prepara-  
5 tion, propagation, compounding, or processing of a drug:

6 “(A) IN GENERAL.—Every establishment that  
7 is required to be registered with the Secretary under  
8 this section shall be subject to inspection pursuant  
9 to section 704.

10 “(B) RISK-BASED SCHEDULE.—In the case of  
11 an establishment that is engaged in the manufac-  
12 ture, preparation, propagation, compounding, or  
13 processing of a drug or drugs (referred to in this  
14 subsection as a ‘drug establishment’), the inspec-  
15 tions required under subparagraph (A) shall be con-  
16 ducted by officers or employees duly designated by  
17 the Secretary, on a risk-based schedule established  
18 by the Secretary.

19 “(C) RISK FACTORS.—In establishing the risk-  
20 based schedule under subparagraph (B), the Sec-  
21 retary shall allocate resources to inspect establish-  
22 ments according to the known safety risks of such  
23 establishments, based on the following factors:

24 “(i) The compliance history of the estab-  
25 lishment.

1           “(ii) The inspection frequency and history  
2           of the establishment, including whether it has  
3           been inspected pursuant to section 704 within  
4           the last four years.

5           “(iii) The record, history, and nature of re-  
6           calls linked to the establishment.

7           “(iv) The inherent risk of the drug manu-  
8           factured, prepared, propagated, compounded, or  
9           processed at the establishment.

10          “(v) Any other criteria deemed necessary  
11          and appropriate by the Secretary for purposes  
12          of allocating inspection resources.

13          “(D) EFFECT OF STATUS.—In determining the  
14          risk associated with an establishment for purposes of  
15          establishing a risk-based schedule under subpara-  
16          graph (B), the Secretary shall not consider whether  
17          the drugs manufactured, prepared, propagated, com-  
18          pounded, or processed by such establishment are  
19          drugs described in section 503(b)(1).

20          “(E) ANNUAL REPORT ON INSPECTIONS OF ES-  
21          TABLISHMENTS.—Not later than February 1 of each  
22          year, the Secretary shall submit to Congress a re-  
23          port that contains the following:

1           “(i) The number of domestic and foreign  
2 establishments registered pursuant to this sec-  
3 tion in the previous calendar year.

4           “(ii) The number of such registered domes-  
5 tic and foreign establishments that the Sec-  
6 retary inspected in the previous calendar year.

7           “(iii) The number of such registered estab-  
8 lishments that list one or more drugs approved  
9 pursuant to an application filed under section  
10 505(j).

11           “(iv) The number of such registered estab-  
12 lishments that list one or more drugs approved  
13 pursuant to an application filed under section  
14 505(b).

15           “(v) The number of registered establish-  
16 ments that list both drug products approved  
17 pursuant to an application filed under section  
18 505(j) and drug products approved pursuant to  
19 an application filed under section 505(b).

20           “(vi) A description of how the Secretary  
21 implemented the risk-based schedule under sub-  
22 paragraph (B) utilizing the factors under sub-  
23 paragraph (C).

24           “(F) PUBLIC AVAILABILITY OF ANNUAL RE-  
25 PORTS.—The Secretary shall make the report re-

1       quired under subparagraph (E) available to the pub-  
2       lic on the Internet Web site of the Food and Drug  
3       Administration.”.

4       **SEC. 803. DRUG SUPPLY QUALITY AND SAFETY.**

5       Paragraph (a) of section 501 (21 U.S.C. 351) is  
6       amended by adding at the end the following: “For pur-  
7       poses of subparagraph (2)(B), the term ‘current good  
8       manufacturing practice’ includes the implementation of  
9       oversight and controls over the manufacture of drugs to  
10      ensure quality, including managing the risk of and estab-  
11      lishing the safety of raw materials, materials used in the  
12      manufacturing of drugs, and finished drug products.”.

13      **SEC. 804. PROHIBITION AGAINST DELAYING, DENYING, LIM-**  
14                                   **ITING, OR REFUSING INSPECTION.**

15      (a) IN GENERAL.—Section 501 (21 U.S.C. 351) is  
16      amended by adding at the end the following:

17      “(j) If it is a drug and it has been manufactured,  
18      processed, packed, or held in any factory, warehouse, or  
19      establishment and the owner, operator, or agent of such  
20      factory, warehouse, or establishment delays, denies, or  
21      limits an inspection, or refuses to permit entry or inspec-  
22      tion.”.

23      (b) GUIDANCE.—Not later than 1 year after the date  
24      of enactment of this section, the Secretary of Health and  
25      Human Services shall issue guidance that defines the cir-

1 cumstances that would constitute delaying, denying, or  
2 limiting inspection, or refusing to permit entry or inspec-  
3 tion, for purposes of section 501(j) of the Federal Food,  
4 Drug, and Cosmetic Act (as added by subsection (a)).

5 **SEC. 805. DESTRUCTION OF ADULTERATED, MISBRANDED,**  
6 **OR COUNTERFEIT DRUGS OFFERED FOR IM-**  
7 **PORT.**

8 (a) IN GENERAL.—The sixth sentence of section  
9 801(a) (21 U.S.C. 381(a)) is amended by inserting before  
10 the period at the end the following: “, except that the Sec-  
11 retary of Health and Human Services, in consultation with  
12 the Secretary of Homeland Security, may cause the de-  
13 struction, without the opportunity for export, of any drug  
14 refused admission that has reasonable probability of caus-  
15 ing serious adverse health consequences or death, as deter-  
16 mined by the Secretary of Health and Human Services,  
17 or that is valued at an amount that is \$2,000 or less (or  
18 such higher amount as the Secretary of Homeland Secu-  
19 rity may set by regulation pursuant to section 1498 of  
20 title 19, United States Code)”.

21 (b) NOTICE.—Section 801(a) (21 U.S.C. 381(a)), as  
22 amended by subsection (a), is further amended by insert-  
23 ing after the sixth sentence the following: “The Secretary  
24 of Health and Human Services shall issue regulations pro-  
25 viding for notice and an opportunity for a hearing on the

1 destruction of a drug under the previous sentence. For a  
2 drug with a value less than and or equal to \$2,000 (or,  
3 as described in the sixth sentence of this subsection, such  
4 higher amount as the Secretary of Homeland Security  
5 may set by regulation pursuant to section 1498 of title  
6 19, United States Code) the regulations under the pre-  
7 vious sentence shall provide for prompt notice and an op-  
8 portunity for a hearing for the owner or consignee before  
9 or after the destruction has occurred. For a drug with a  
10 value greater than \$2,000 (or, as described in the sixth  
11 sentence of this subsection, such higher amount as the  
12 Secretary of Homeland Security may set by regulation  
13 pursuant to section 1498 of title 19, United States Code)  
14 that has reasonable probability of causing serious adverse  
15 health consequences or death as determined by the Sec-  
16 retary of Health and Human Services, the regulations  
17 under the seventh sentence of this subsection shall provide  
18 for notice and an opportunity for a hearing to the owner  
19 or consignee before the destruction occurs.”.

20 (c) RESTITUTION.—In the regulations described in  
21 the seventh sentence of section 801(a) of the Federal  
22 Food, Drug, and Cosmetic Act (as added by subsection  
23 (b)), the Secretary of Health and Human Services shall  
24 establish an administrative process whereby an owner or  
25 consignee of a drug destroyed without an opportunity for

1 a hearing on destruction may obtain restitution for the  
2 value of the drug destroyed under the sixth sentence of  
3 such section upon demonstration that such drug was  
4 wrongfully destroyed.

5 (d) CONFORMING AMENDMENT.—The first sentence  
6 of section 801(a) (21 U.S.C. 381(a)) is amended by insert-  
7 ing “, except as otherwise described in the sixth and sev-  
8 enth sentences of this subsection,” after “giving notice  
9 thereof”.

10 **SEC. 806. ADMINISTRATIVE DETENTION.**

11 (a) IN GENERAL.—Section 304(g) (21 U.S.C.  
12 335a(g)) is amended—

13 (1) in paragraph (1), by inserting “, drug,”  
14 after “device”, each place it appears;

15 (2) in paragraph (2)(A), by inserting “, drug,”  
16 after “(B), a device”; and

17 (3) in paragraph (2)(B), by inserting “or drug”  
18 after “device” each place it appears.

19 (b) REGULATION.—Not later than 2 years after the  
20 date of the enactment of this Act, the Secretary of Health  
21 and Human Services shall promulgate regulations to im-  
22 plement administrative detention authority with respect to  
23 drugs, as authorized by the amendments made by sub-  
24 section (a). Before promulgating such regulations, the



1 Secretary shall consult with stakeholders, including manu-  
2 facturers of drugs.

3 (c) EFFECTIVE DATE.—The amendments made by  
4 subsection (a) shall not take effect until the Secretary has  
5 issued a final regulation under subsection (b).

6 **SEC. 807. ENHANCED CRIMINAL PENALTY FOR COUNTER-**  
7 **FEIT DRUGS.**

8 (a) IN GENERAL.—Section 303(a) (21 U.S.C.  
9 333(a)) is amended by adding at the end the following:  
10 “(3) Notwithstanding paragraph (2), any person who  
11 engages in any conduct described in section 301(i)(2)  
12 knowing or having reason to know that the conduct con-  
13 cerns the rendering of a drug as a counterfeit drug, or  
14 who engages in conduct described in section 301(i)(3)  
15 knowing or having reason to know that the conduct will  
16 cause a drug to be a counterfeit drug or knowing or having  
17 reason to know that a drug held, sold, or dispensed is a  
18 counterfeit drug, shall be fined in accordance with title  
19 18, United States Code, or imprisoned not more than 20  
20 years, or both, except that if the use of the counterfeit  
21 drug by a consumer is the proximate cause of the death  
22 of the consumer, the term of imprisonment shall be any  
23 term of years or for life.”.

24 (b) CONFORMING AMENDMENT.—Section 201(g)(2)  
25 (21 U.S.C. 321(g)(2)) is amended by adding at the end

1 the following sentence: “The term ‘counterfeit drug’ shall  
2 not include a drug or placebo intended for use in a clinical  
3 trial that is intentionally labeled or marked to maintain  
4 proper blinding of the study.”.

5 **SEC. 808. UNIQUE FACILITY IDENTIFICATION NUMBER.**

6 (a) DOMESTIC ESTABLISHMENTS.—Section 510 (21  
7 U.S.C. 360) is amended—

8 (1) in subsection (b)(1), by striking “and all  
9 such establishments” and inserting “all such estab-  
10 lishments, and the unique facility identifier of each  
11 such establishment”; and

12 (2) in subsection (c), by striking “and such es-  
13 tablishment” and inserting “such establishment, and  
14 the unique facility identifier of such establishment”.

15 (b) FOREIGN ESTABLISHMENTS.—Subparagraph (A)  
16 of section 510(i)(1) (21 U.S.C. 360(i)(1)) is amended by  
17 inserting “the unique facility identifier of the establish-  
18 ment,” after “the name and place of business of the estab-  
19 lishment,”.

20 (c) GUIDANCE.—Section 510 (21 U.S.C. 360) is  
21 amended by adding at the end the following:

22 “(q) GUIDANCE ON SUBMISSION OF UNIQUE FACIL-  
23 ITY IDENTIFIERS.—

1           “(1) IN GENERAL.—Not later than 2 years  
2           after the date of the enactment of this subsection,  
3           the Secretary shall, by guidance, specify—

4                   “(A) the unique facility identifier system  
5           to be used to meet the requirements of—

6                           “(i) subsections (b)(1), (c), and  
7                           (i)(1)(A) of this section; and

8                           “(ii) section 801(s) (relating to reg-  
9                           istration of commercial importers); and

10                   “(B) the form, manner, and timing of sub-  
11           missions of unique facility identifiers under the  
12           provisions specified in subparagraph (A).

13           “(2) CONSIDERATION.—In developing the guid-  
14           ance under paragraph (1), the Secretary shall take  
15           into account the utilization of existing unique identi-  
16           fication schemes and compatibility with customs  
17           automated systems.”.

18           (d) IMPORTATION.—Section 801(a) (21 U.S.C.  
19           381(a)) is amended by inserting “or (5) for an article that  
20           is a drug, the appropriate unique facility identifiers under  
21           subsection (s) (relating to commercial importers) and sec-  
22           tion 510(i) (relating to foreign establishments), as speci-  
23           fied by the Secretary, are not provided,” before “then such  
24           article shall be refused admission”.

1 **SEC. 809. DOCUMENTATION FOR ADMISSIBILITY OF IM-**  
2 **PORTS.**

3 Section 801 (21 U.S.C. 381) is amended by adding  
4 at the end the following:

5 “(r) DOCUMENTATION.—

6 “(1) SUBMISSION.—The Secretary may require,  
7 in consultation with the Secretary of Homeland Se-  
8 curity acting through U.S. Customs and Border Pro-  
9 tection as determined appropriate by the Secretary,  
10 the submission of documentation or other informa-  
11 tion for a drug that is imported or offered for im-  
12 port into the United States.

13 “(2) REFUSAL OF ADMISSION.—A drug im-  
14 ported or offered for import into the United States  
15 shall be refused admission unless all documentation  
16 and information the Secretary requires under this  
17 Act, the Public Health Service Act, or both, as ap-  
18 propriate, for such article is submitted.

19 “(3) REGULATIONS.—

20 “(A) DOCUMENTS AND INFORMATION.—

21 The Secretary shall issue a regulation to specify  
22 the documentation or other information that is  
23 described in paragraph (1). Such information  
24 may include—

25 “(i) information demonstrating the  
26 regulatory status of the drug, such as the

1 new drug application, abbreviated new  
2 drug application, or investigational new  
3 drug or Drug Master File number;

4 “(ii) facility information, such as  
5 proof of registration and the unique facility  
6 identifier; and

7 “(iii) indication of compliance with  
8 current good manufacturing practice, such  
9 as satisfactory testing results, certifi-  
10 cations relating to satisfactory inspections,  
11 and compliance with the country of export  
12 regulations.

13 “(B) EXEMPTION.—The Secretary may, by  
14 regulation, exempt drugs imported for research  
15 purposes only and other types of drug imports  
16 from some or all of the requirements of this  
17 subsection.

18 “(4) EFFECTIVE DATE.—The final rule under  
19 paragraph (3)(A) shall take effect not less than 180  
20 days after the Secretary promulgates such final  
21 rule.”.

22 **SEC. 810. REGISTRATION OF COMMERCIAL IMPORTERS.**

23 (a) PROHIBITIONS.—Section 301 (21 U.S.C. 331) is  
24 amended by adding at the end the following:

1       “(aaa) The failure to register in accordance with sec-  
2       tion 801(s).”.

3       (b) REGISTRATION.—Section 801 (21 U.S.C. 381),  
4       as amended by section 810, is further amended by adding  
5       at the end the following:

6       “(s) REGISTRATION OF COMMERCIAL IMPORTERS.—

7               “(1) REGISTRATION.—The Secretary shall re-  
8       quire a commercial importer of drugs—

9               “(A) to be registered with the Secretary in  
10              a form and manner specified by the Secretary;  
11              and

12              “(B) consistent with the guidance under  
13              section 510(q), to submit, at the time of reg-  
14              istration, a unique identifier for the principal  
15              place of business for which the importer is re-  
16              quired to register under this subsection.

17       “(2) REGULATIONS.—

18              “(A) IN GENERAL.—The Secretary, in con-  
19              sultation with the Secretary of Homeland Secu-  
20              rity acting through U.S. Customs and Border  
21              Protection, shall promulgate regulations to es-  
22              tablish good importer practices that specify the  
23              measures an importer shall take to ensure im-  
24              ported drugs are in compliance with the re-

1           quirements of this Act and the Public Health  
2           Service Act.

3           “(B) EXPEDITED CLEARANCE FOR CER-  
4           TAIN IMPORTERS.—In promulgating good im-  
5           porter practice regulations under subparagraph  
6           (A), the Secretary may, as appropriate, take  
7           into account differences among importers and  
8           types of imports, and, based on the level of risk  
9           posed by the imported drug, provide for expe-  
10          dited clearance for those importers that volun-  
11          teer to participate in partnership programs for  
12          highly compliant companies.

13          “(3) DISCONTINUANCE OF REGISTRATION.—  
14          The Secretary shall discontinue the registration of  
15          any commercial importer of drugs that fails to com-  
16          ply with the regulations promulgated under this sub-  
17          section.

18          “(4) EXEMPTIONS.—The Secretary, by notice  
19          in the Federal Register, may establish exemptions  
20          from the requirements of this subsection.”.

21          (c) MISBRANDING.—Section 502(o) (21 U.S.C. 352)  
22          is amended by inserting “if it is a drug and was imported  
23          or offered for import by a commercial importer of drugs  
24          not duly registered under section 801(s),” after “not duly  
25          registered under section 510,”.

1 (d) REGULATIONS.—

2 (1) IN GENERAL.—Not later than 36 months  
3 after the date of the enactment of this Act, the Sec-  
4 retary of Health and Human Services, in consulta-  
5 tion with the Secretary of Homeland Security acting  
6 through U.S. Customs and Border Protection, shall  
7 promulgate the regulations required to carry out sec-  
8 tion 801(s) of the Federal Food, Drug, and Cos-  
9 metic Act, as added by subsection (b).

10 (2) EFFECTIVE DATE.—In establishing the ef-  
11 fective date of the regulations under paragraph (1),  
12 the Secretary of Health and Human Services shall,  
13 in consultation with the Secretary of Homeland Se-  
14 curity acting through U.S. Customs and Border Pro-  
15 tection, as determined appropriate by the Secretary  
16 of Health and Human Services, provide a reasonable  
17 period of time for an importer of a drug to comply  
18 with good importer practices, taking into account  
19 differences among importers and types of imports,  
20 including based on the level of risk posed by the im-  
21 ported product.

22 **SEC. 811. NOTIFICATION.**

23 (a) PROHIBITED ACTS.—Section 301 (21 U.S.C.  
24 331), as amended by section 811, is further amended by  
25 adding at the end the following:



1 “(bbb) The failure to notify the Secretary in violation  
2 of section 568.”.

3 (b) NOTIFICATION.—Subchapter E of chapter V (21  
4 U.S.C. 360bbb et seq.) is amended by adding at the end  
5 the following:

6 **“SEC. 568 NOTIFICATION.**

7 “(a) NOTIFICATION TO SECRETARY.—With respect  
8 to a drug, the Secretary may require notification to the  
9 Secretary by a regulated person if the regulated person  
10 knows—

11 “(1) that the use of such drug in the United  
12 States may result in serious injury or death;

13 “(2) of a significant loss or known theft of such  
14 drug intended for use in the United States; or

15 “(3) that—

16 “(A) such drug has been or is being coun-  
17 terfeited; and

18 “(B)(i) the counterfeit product is in com-  
19 merce in the United States or could be reason-  
20 ably expected to be introduced into commerce;  
21 or

22 “(ii) such drug has been or is being im-  
23 ported into the United States or may reason-  
24 ably be expected to be offered for import into  
25 the United States.

1       “(b) MANNER OF NOTIFICATION.—Notification  
2 under this section shall be made in such manner and by  
3 such means as the Secretary may specify by regulation  
4 or guidance.

5       “(c) SAVINGS CLAUSE.—Nothing in this section shall  
6 be construed as limiting any other authority of the Sec-  
7 retary to require notifications related to a drug under any  
8 other provision of this Act or the Public Health Service  
9 Act.

10       “(d) DEFINITION.—In this section, the term ‘regu-  
11 lated person’ means—

12               “(1) a person who is required to register under  
13 section 510 or 801(s);

14               “(2) a wholesale distributor of a drug product;  
15 or

16               “(3) any other person that distributes drugs ex-  
17 cept a person that distributes drugs exclusively for  
18 retail sale.”.

19 **SEC. 812. EXCHANGE OF INFORMATION.**

20 Section 708 (21 U.S.C. 379) is amended—

21               (1) by striking “The Secretary may provide”  
22 and inserting the following:

23               “(a) CONTRACTORS.—The Secretary may provide”;  
24 and

25               (2) by adding at the end the following:

1       “(b) ABILITY TO RECEIVE AND PROTECT CON-  
2 FIDENTIAL INFORMATION.—Except pursuant to an order  
3 of a court of the United States, the Secretary shall not  
4 be required to disclose under section 552 of title 5, United  
5 States Code, or any other provision of law, any informa-  
6 tion relating to drugs obtained from a Federal, State, or  
7 local government agency, or from a foreign government  
8 agency, if the agency has requested that the information  
9 be kept confidential. For purposes of section 552 of title  
10 5, United States Code, this subsection shall be considered  
11 a statute described in section 552(b)(3)(B).

12       “(c) AUTHORITY TO ENTER INTO MEMORANDA OF  
13 UNDERSTANDING FOR PURPOSES OF INFORMATION EX-  
14 CHANGE.—The Secretary may enter into written agree-  
15 ments regarding the exchange of information referenced  
16 in section 301(j) subject to the following criteria:

17               “(1) CERTIFICATION.—The Secretary may only  
18 enter into written agreements under this subsection  
19 with foreign governments that the Secretary has cer-  
20 tified as having the authority and demonstrated abil-  
21 ity to protect trade secret information from disclo-  
22 sure. Responsibility for this certification shall not be  
23 delegated to any officer or employee other than the  
24 Commissioner of Food and Drugs.

1           “(2) WRITTEN AGREEMENT.—The written  
2           agreement under this subsection shall include a com-  
3           mitment by the foreign government to protect infor-  
4           mation exchanged under this subsection from disclo-  
5           sure unless and until the sponsor gives written per-  
6           mission for disclosure or the Secretary makes a dec-  
7           laration of a public health emergency pursuant to  
8           section 319 of the Public Health Service Act that is  
9           relevant to the information.

10           “(3) INFORMATION EXCHANGE.—The Secretary  
11           may provide to a foreign government that has been  
12           certified under paragraph (1), and that has executed  
13           a written agreement under paragraph (2), informa-  
14           tion referenced in section 301(j) in the following cir-  
15           cumstances:

16                   “(A) Information concerning the inspection  
17                   of a facility may be provided if—

18                           “(i) the Secretary reasonably believes,  
19                           or the written agreement described in  
20                           paragraph (2) establishes, that the govern-  
21                           ment has authority to otherwise obtain  
22                           such information; and

23                           “(ii) the written agreement executed  
24                           under paragraph (2) limits the recipient’s

1 use of the information to the recipient's  
2 civil regulatory purposes.

3 “(B) Information not described in sub-  
4 paragraph (A) may be provided as part of an  
5 investigation, or to alert the foreign government  
6 to the potential need for an investigation, if the  
7 Secretary has reasonable grounds to believe  
8 that a drug has a reasonable probability of  
9 causing serious adverse health consequences or  
10 death.

11 “(d) NO LIMITATION ON AUTHORITY.—This section  
12 shall not affect the authority of the Secretary to provide  
13 or disclose information under any other provision of law.”.

14 **SEC. 813. EXTRATERRITORIAL JURISDICTION.**

15 Chapter III (21 U.S.C. 331 et seq.) is amended by  
16 adding at the end the following:

17 **“SEC. 311. EXTRATERRITORIAL JURISDICTION.**

18 “There is extraterritorial jurisdiction over any viola-  
19 tion of this Act relating to any article regulated under this  
20 Act if such article was intended for import into the United  
21 States or if any act in furtherance of the violation was  
22 committed in the United States.”.

1 **SEC. 814. PROTECTION AGAINST INTENTIONAL ADULTERA-**  
2 **TION.**

3 Section 303(b) (21 U.S.C. 333(b)) is amended by  
4 adding at the end the following:

5 “(7) Notwithstanding subsection (a)(2), any  
6 person that knowingly and intentionally engages in  
7 an activity that results in a drug becoming adulter-  
8 ated under subsection (a)(1), (b), (c), or (d) of sec-  
9 tion 501 and having a reasonable probability of  
10 causing serious adverse health consequences or  
11 death shall be imprisoned for not more than 20  
12 years or fined not more than \$1,000,000, or both.”.

13 **SEC. 815. RECORDS FOR INSPECTION.**

14 Section 704(a) (21 U.S.C. 374(a)) is amended by  
15 adding at the end the following:

16 “(4)(A) Any records or other information that the  
17 Secretary may inspect under this section from a person  
18 that owns or operates an establishment that is engaged  
19 in the manufacture, preparation, propagation,  
20 compounding, or processing of a drug shall, upon the re-  
21 quest of the Secretary, be provided to the Secretary by  
22 such person, in advance of or in lieu of an inspection, with-  
23 in a reasonable timeframe, within reasonable limits, and  
24 in a reasonable manner, and in either electronic or phys-  
25 ical form, at the expense of such person. The Secretary’s

1 request shall include a sufficient description of the records  
2 requested.

3 “(B) Upon receipt of the records requested under  
4 subparagraph (A), the Secretary shall provide to the per-  
5 son confirmation of receipt.

6 “(C) Nothing in this paragraph supplants the author-  
7 ity of the Secretary to conduct inspections otherwise per-  
8 mitted under this Act in order to ensure compliance with  
9 this Act.”.

## 10 **Subtitle B—Medical Gas Safety**

### 11 **SEC. 821. REGULATION OF MEDICAL GASES.**

12 Chapter V (21 U.S.C. 351 et seq.) is amended by  
13 adding at the end the following:

### 14 **“Subchapter G—Medical Gases**

#### 15 **“SEC. 575. DEFINITIONS.**

16 “In this subchapter:

17 “(1) The term ‘designated medical gas’ means  
18 any of the following:

19 “(A) Oxygen that meets the standards set  
20 forth in an official compendium.

21 “(B) Nitrogen that meets the standards  
22 set forth in an official compendium.

23 “(C) Nitrous oxide that meets the stand-  
24 ards set forth in an official compendium.

1           “(D) Carbon dioxide that meets the stand-  
2           ards set forth in an official compendium.

3           “(E) Helium that meets the standards set  
4           forth in an official compendium.

5           “(F) Carbon monoxide that meets the  
6           standards set forth in an official compendium.

7           “(G) Medical air that meets the standards  
8           set forth in an official compendium.

9           “(H) Any other medical gas deemed appro-  
10          priate by the Secretary, after taking into ac-  
11          count any investigational new drug application  
12          or investigational new animal drug application  
13          for the same medical gas submitted in accord-  
14          ance with regulations applicable to such appli-  
15          cations in title 21 of the Code of Federal Regu-  
16          lations, unless any period of exclusivity under  
17          section 505(c)(3)(E)(ii) or section  
18          505(j)(5)(F)(ii), or the extension of any such  
19          period under section 505A, applicable to such  
20          medical gas has not expired.

21          “(2) The term ‘medical gas’ means a drug  
22          that—

23               “(A) is manufactured or stored in a lique-  
24               fied, nonliquefied, or cryogenic state; and

25               “(B) is administered as a gas.



1 **“SEC. 576. REGULATION OF MEDICAL GASES.**

2 “(a) CERTIFICATION OF DESIGNATED MEDICAL  
3 GASES.—

4 “(1) SUBMISSION.—Beginning 180 days after  
5 the date of enactment of this section, any person  
6 may file with the Secretary a request for certifi-  
7 cation of a medical gas as a designated medical gas.  
8 Any such request shall contain the following infor-  
9 mation:

10 “(A) A description of the medical gas.

11 “(B) The name and address of the spon-  
12 sor.

13 “(C) The name and address of the facility  
14 or facilities where the medical gas is or will be  
15 manufactured.

16 “(D) Any other information deemed appro-  
17 priate by the Secretary to determine whether  
18 the medical gas is a designated medical gas.

19 “(2) GRANT OF CERTIFICATION.—The certifi-  
20 cation requested under paragraph (1) is deemed to  
21 be granted unless, within 60 days of the filing of  
22 such request, the Secretary finds that—

23 “(A) the medical gas subject to the certifi-  
24 cation is not a designated medical gas;

25 “(B) the request does not contain the in-  
26 formation required under paragraph (1) or oth-

erwise lacks sufficient information to permit the Secretary to determine that the medical gas is a designated medical gas; or

“(C) denying the request is necessary to protect the public health.

“(3) EFFECT OF CERTIFICATION.—

“(A) IN GENERAL.—

“(i) APPROVED USES.—A designated medical gas for which a certification is granted under paragraph (2) is deemed, alone or in combination, as medically appropriate, with another designated medical gas or gases for which a certification or certifications have been granted, to have in effect an approved application under section 505 or 512, subject to all applicable post-approval requirements, for the following indications for use:

“(I) In the case of oxygen, the treatment or prevention of hypoxemia or hypoxia.

“(II) In the case of nitrogen, use in hypoxic challenge testing.

“(III) In the case of nitrous oxide, analgesia.

1                   “(IV) In the case of carbon diox-  
2                   ide, use in extracorporeal membrane  
3                   oxygenation therapy or respiratory  
4                   stimulation.

5                   “(V) In the case of helium, the  
6                   treatment of upper airway obstruction  
7                   or increased airway resistance.

8                   “(VI) In the case of medical air,  
9                   to reduce the risk of hyperoxia.

10                  “(VII) In the case of carbon  
11                  monoxide, use in lung diffusion test-  
12                  ing.

13                  “(VIII) Any other indication for  
14                  use for a designated medical gas or  
15                  combination of designated medical  
16                  gases deemed appropriate by the Sec-  
17                  retary, unless any period of exclusivity  
18                  under clause (iii) or (iv) of section  
19                  505(c)(3)(E), clause (iii) or (iv) of  
20                  section 505(j)(5)(F), or section 527,  
21                  or the extension of any such period  
22                  under section 505A, applicable to  
23                  such indication for use for such gas or  
24                  combination of gases has not expired.

1           “(ii) LABELING.—The requirements  
2           of sections 503(b)(4) and 502(f) are  
3           deemed to have been met for a designated  
4           medical gas if the labeling on final use  
5           container for such medical gas bears—

6                       “(I) the information required by  
7                       section 503(b)(4);

8                       “(II) a warning statement con-  
9                       cerning the use of the medical gas as  
10                      determined by the Secretary by regu-  
11                      lation; and

12                     “(III) appropriate directions and  
13                     warnings concerning storage and han-  
14                     dling.

15           “(B) INAPPLICABILITY OF EXCLUSIVITY  
16           PROVISIONS.—

17                   “(i) NO EXCLUSIVITY FOR A CER-  
18                   TIFIED MEDICAL GAS.—No designated  
19                   medical gas deemed under subparagraph  
20                   (A)(i) to have in effect an approved appli-  
21                   cation is eligible for any period of exclu-  
22                   sivity under section 505(c), 505(j), or 527,  
23                   or the extension of any such period under  
24                   section 505A, on the basis of such deemed  
25                   approval.

1 “(ii) EFFECT ON CERTIFICATION.—

2 No period of exclusivity under section  
3 505(c), 505(j), or section 527, or the ex-  
4 tension of any such period under section  
5 505A, with respect to an application for a  
6 drug product shall prohibit, limit, or other-  
7 wise affect the submission, grant, or effect  
8 of a certification under this section, except  
9 as provided in subsection (a)(3)(A)(i)(VIII)  
10 and section 575(1)(H).

11 “(4) WITHDRAWAL, SUSPENSION, OR REVOCATION OF APPROVAL.—

12  
13 “(A) WITHDRAWAL, SUSPENSION OF APPROVAL.—Nothing in this subchapter limits the  
14 Secretary’s authority to withdraw or suspend  
15 approval of a drug product, including a des-  
16 ignated medical gas deemed under this section  
17 to have in effect an approved application under  
18 section 505 or section 512 of this Act.

19  
20 “(B) REVOCATION OF CERTIFICATION.—

21 The Secretary may revoke the grant of a certifi-  
22 cation under paragraph (2) if the Secretary de-  
23 termines that the request for certification con-  
24 tains any material omission or falsification.

25 “(b) PRESCRIPTION REQUIREMENT.—

1           “(1) IN GENERAL.—A designated medical gas  
2       shall be subject to the requirements of section  
3       503(b)(1) unless the Secretary exercises the author-  
4       ity provided in section 503(b)(3) to remove such  
5       medical gas from the requirements of section  
6       503(b)(1), the gas is approved for use without a pre-  
7       scription pursuant to an application under section  
8       505 or 512, or the use in question is authorized pur-  
9       suant to another provision of this Act relating to use  
10      of medical products in emergencies.

11           “(2) OXYGEN.—

12               “(A) NO PRESCRIPTION REQUIRED FOR  
13       CERTAIN USES.—Notwithstanding paragraph  
14       (1), oxygen may be provided without a prescrip-  
15       tion for the following uses:

16                   “(i) For use in the event of depres-  
17                   surization or other environmental oxygen  
18                   deficiency.

19                   “(ii) For oxygen deficiency or for use  
20                   in emergency resuscitation, when adminis-  
21                   tered by properly trained personnel.

22               “(B) LABELING.—For oxygen provided  
23       pursuant to subparagraph (A), the require-  
24       ments of section 503(b)(4) shall be deemed to  
25       have been met if its labeling bears a warning

1           that the oxygen can be used for emergency use  
2           only and for all other medical applications a  
3           prescription is required.

4   **“SEC. 577. INAPPLICABILITY OF DRUG FEES TO DES-**  
5               **IGNATED MEDICAL GASES.**

6           “A designated medical gas, alone or in combination  
7   with another designated gas or gases (as medically appro-  
8   priate) deemed under section 576 to have in effect an ap-  
9   proved application shall not be assessed fees under section  
10  736(a) on the basis of such deemed approval.”.

11   **SEC. 822. CHANGES TO REGULATIONS.**

12           (a) REPORT.—Not later than 18 months after the  
13   date of the enactment of this Act, the Secretary, after ob-  
14   taining input from medical gas manufacturers and any  
15   other interested members of the public, shall—

16               (1) determine whether any changes to the Fed-  
17           eral drug regulations are necessary for medical  
18           gases; and

19               (2) submit to the Committee on Health, Edu-  
20           cation, Labor and Pensions of the Senate and the  
21           Committee on Energy and Commerce of the House  
22           of Representatives a report regarding any such  
23           changes.

24           (b) REGULATIONS.—If the Secretary determines  
25   under subsection (a) that changes to the Federal drug reg-

1 ulations are necessary for medical gases, the Secretary  
2 shall issue final regulations revising the Federal drug reg-  
3 ulations with respect to medical gases not later than 48  
4 months after the date of the enactment of this Act.

5 (c) DEFINITIONS.—In this section:

6 (1) The term “Federal drug regulations” means  
7 regulations in title 21 of the Code of Federal Regu-  
8 lations pertaining to drugs.

9 (2) The term “medical gas” has the meaning  
10 given to such term in section 575 of the Federal  
11 Food, Drug, and Cosmetic Act, as added by section  
12 821 of this Act.

13 (3) The term “Secretary” means the Secretary  
14 of Health and Human Services, acting through the  
15 Commissioner of Food and Drugs.

16 **SEC. 823. RULES OF CONSTRUCTION.**

17 Nothing in this subtitle and the amendments made  
18 by this subtitle applies with respect to—

19 (1) a drug that is approved prior to May 1,  
20 2012, pursuant to an application submitted under  
21 section 505 or 512 of the Federal Food, Drug, and  
22 Cosmetic Act (21 U.S.C. 355, 360b);

23 (2) any gas listed in subparagraphs (A) through  
24 (G) of section 575(1) of the Federal Food, Drug,  
25 and Cosmetic Act, as added by section 821 of this



1 Act, or any combination of any such gases, for an  
2 indication that—

3 (A) is not included in, or is different from,  
4 those specified in subclauses (I) through (VII)  
5 of section 576(a)(3)(A)(i) of such Act; and

6 (B) is approved on or after May 1, 2012,  
7 pursuant to an application submitted under  
8 Section 505 or 512; or

9 (3) any designated medical gas added pursuant  
10 to subparagraph (H) of section 575(1) of such Act  
11 for an indication that—

12 (A) is not included in, or is different from,  
13 those originally added pursuant to subpara-  
14 graph (H) of section 575(1) and section  
15 576(a)(3)(A)(i)(VIII); and

16 (B) is approved on or after May 1, 2012,  
17 pursuant to an application submitted under sec-  
18 tion 505 or 512 of such Act.

## 19 **Subtitle C—Generating Antibiotic** 20 **Incentives Now**

### 21 **SEC. 831. EXTENSION OF EXCLUSIVITY PERIOD FOR DRUGS.**

22 (a) IN GENERAL.—The Federal Food, Drug, and  
23 Cosmetic Act is amended by inserting after section 505D  
24 (21 U.S.C. 355e) the following:

1   **“SEC. 505E. EXTENSION OF EXCLUSIVITY PERIOD FOR NEW**  
2                   **QUALIFIED INFECTIOUS DISEASE PRODUCTS.**

3           “(a) EXTENSION.—If the Secretary approves an ap-  
4   plication pursuant to section 505 for a drug that has been  
5   determined to be a qualified infectious disease product  
6   under subsection (d), then the four- and five-year periods  
7   described in subsections (c)(3)(E)(ii) and (j)(5)(F)(ii) of  
8   section 505, the three-year periods described in clauses  
9   (iii) and (iv) of subsection (c)(3)(E) and clauses (iii) and  
10   (iv) of subsection (j)(5)(F) of section 505, or the seven  
11   year period described in section 527, as applicable, shall  
12   be extended by five years.

13          “(b) RELATION TO PEDIATRIC EXCLUSIVITY.—Any  
14   extension under subsection (a) of a period shall be in addi-  
15   tion to any extension of the period under section 505A  
16   with respect to the drug.

17          “(c) LIMITATIONS.—Subsection (a) does not apply to  
18   the approval of—

19               “(1) a supplement to an application under sec-  
20   tion 505(b) for any qualified infectious disease prod-  
21   uct for which an extension described in subsection  
22   (a) is in effect or has expired;

23               “(2) a subsequent application filed by the same  
24   sponsor or manufacturer of a qualified infectious  
25   disease product described in paragraph (1) (or a li-

1        censor, predecessor in interest, or other related enti-  
2        ty) for—

3                “(A) a change (not including a modifica-  
4                tion to the active moiety of the qualified infec-  
5                tious disease product) that results in a new in-  
6                dication, route of administration, dosing sched-  
7                ule, dosage form, delivery system, delivery de-  
8                vice, or strength; or

9                “(B) a modification to the active moiety of  
10              the qualified infectious disease product that  
11              does not result in a change in safety or effec-  
12              tiveness; or

13              “(3) a product that does not meet the definition  
14              of a qualified infectious disease product under sub-  
15              section (f) based upon its approved uses.

16              “(d) DETERMINATION.—The manufacturer or spon-  
17              sor of a drug may request that the Secretary designate  
18              a drug as a qualified infectious disease product at any  
19              time in the drug development process prior to the submis-  
20              sion of an application under section 505(b) for the drug,  
21              but not later than 45 days before the submission of such  
22              application. The Secretary shall, not later than 30 days  
23              after the submission of such request, determine whether  
24              the drug is a qualified infectious disease product.

1       “(e) REGULATIONS.—The Secretary shall promulgate  
2 regulations for carrying out this section. The Secretary  
3 shall promulgate the initial regulations for carrying out  
4 this section not later than 12 months after the date of  
5 the enactment of this section.

6       “(f) DEFINITIONS.—In this section:

7           “(1) QUALIFIED INFECTIOUS DISEASE PROD-  
8 UCT.—The term ‘qualified infectious disease prod-  
9 uct’ means an antibacterial or antifungal drug for  
10 human use that treats or prevents an infection  
11 caused by a qualifying pathogen.

12           “(2) QUALIFYING PATHOGEN.—The term  
13 ‘qualifying pathogen’ means—

14           “(A) resistant gram-positive pathogens, in-  
15 cluding methicillin-resistant *Staphylococcus*  
16 *aureus* (MRSA), vancomycin-resistant *Staphy-*  
17 *lococcus aureus* (VRSA), and vancomycin-resist-  
18 ant enterococcus (VRE);

19           “(B) multidrug resistant gram-negative  
20 bacteria, including *Acinetobacter*, *Klebsiella*,  
21 *Pseudomonas*, and *E. coli* species;

22           “(C) multi-drug resistant tuberculosis; or

23           “(D) any other infectious pathogen identi-  
24 fied for purposes of this section by the Sec-  
25 retary.”.

1 (b) APPLICATION.—Section 505E of the Federal  
2 Food, Drug, and Cosmetic Act, as added by subsection  
3 (a), applies only with respect to a drug that is first ap-  
4 proved under section 505(c) of such Act (21 U.S.C.  
5 355(c)) on or after the date of the enactment of this Act.

6 **SEC. 832. STUDY ON INCENTIVES FOR QUALIFIED INFEC-**  
7 **TIOUS DISEASE BIOLOGICAL PRODUCTS.**

8 (a) IN GENERAL.—The Comptroller General of the  
9 United States shall—

10 (1) conduct a study on the need for incentives  
11 to encourage research on and development and mar-  
12 keting of qualified infectious disease biological prod-  
13 ucts; and

14 (2) not later than 1 year after the date of the  
15 enactment of this Act, submit a report to the Con-  
16 gress on the results of such study, including any rec-  
17 ommendations of the Comptroller General on appro-  
18 priate incentives for addressing such need.

19 (b) DEFINITIONS.—In this section:

20 (1) The term “biological product” has the  
21 meaning given to such term in section 351 of the  
22 Public Health Service Act (42 U.S.C. 262).

23 (2) The term “qualified infectious disease bio-  
24 logical product” means a biological product for

1 human use that treats or prevents an infection  
2 caused by a qualifying pathogen.

3 (3) The term “qualifying pathogen” has the  
4 meaning given to such term in section 505E of the  
5 Federal Food, Drug, and Cosmetic Act, as added by  
6 section 831 of this Act.

7 **SEC. 833. CLINICAL TRIALS.**

8 (a) REVIEW AND REVISION OF GUIDELINES.—

9 (1) IN GENERAL.—Not later than 1 year after  
10 the date of the enactment of this Act, and not later  
11 than 4 years thereafter, the Secretary shall—

12 (A) review the guidance of the Food and  
13 Drug Administration for the conduct of clinical  
14 trials with respect to antibacterial and  
15 antifungal drugs; and

16 (B) as appropriate, revise such guidance to  
17 reflect developments in scientific and medical  
18 information and technology and to ensure clar-  
19 ity regarding the procedures and requirements  
20 for approval of an antibiotic and antifungal  
21 drug under chapter V of the Federal Food,  
22 Drug, and Cosmetic Act (21 U.S.C. 351 et  
23 seq.).

24 (2) ISSUES FOR REVIEW.—At a minimum, the  
25 review under paragraph (1) shall address the appro-

1        piate animal models of infection, in vitro tech-  
2        niques, valid microbiological surrogate markers, the  
3        use of noninferiority versus superiority trials, and  
4        appropriate delta values for noninferiority trials.

5            (3) RULE OF CONSTRUCTION.—Except to the  
6        extent to which the Secretary of Health and Human  
7        Services makes revisions under paragraph (1)(B),  
8        nothing in this section shall be construed to repeal  
9        or otherwise affect the guidance of the Food and  
10       Drug Administration.

11        (b) RECOMMENDATIONS FOR INVESTIGATIONS.—

12            (1) REQUEST.—The sponsor of a drug intended  
13        to be used to treat or prevent a qualifying pathogen  
14        may request that the Secretary provide written rec-  
15        ommendations for nonclinical and clinical investiga-  
16        tions which may be conducted with the drug before  
17        it may be approved for such use under section 505  
18        of the Federal Food, Drug, and Cosmetic Act (21  
19        U.S.C. 355).

20            (2) RECOMMENDATIONS.—If the Secretary has  
21        reason to believe that a drug for which a request is  
22        made under this subsection is a qualified infectious  
23        disease product, the Secretary shall provide the per-  
24        son making the request written recommendations for  
25        the nonclinical and clinical investigations which the

1 Secretary believes, on the basis of information avail-  
2 able to the Secretary at the time of the request,  
3 would be necessary for approval under section 505  
4 of the Federal Food, Drug, and Cosmetic Act (21  
5 U.S.C. 355) of such drug for the use described in  
6 paragraph (1).

7 (c) DEFINITIONS.—In this section:

8 (1) The term “drug” has the meaning given to  
9 such term in section 201 of the Federal Food, Drug,  
10 and Cosmetic Act (21 U.S.C. 321).

11 (2) The term “qualified infectious disease prod-  
12 uct” has the meaning given to such term in section  
13 505E of the Federal Food, Drug, and Cosmetic Act,  
14 as added by section 831 of this Act.

15 (3) The term “qualifying pathogen” has the  
16 meaning given to such term in section 505E of the  
17 Federal Food, Drug, and Cosmetic Act, as added by  
18 section 831 of this Act.

19 (4) The term “Secretary” means the Secretary  
20 of Health and Human Services, acting through the  
21 Commissioner of Food and Drugs.

22 **SEC. 834. REASSESSMENT OF QUALIFIED INFECTIOUS DIS-**  
23 **EASE PRODUCT INCENTIVES IN 5 YEARS.**

24 Not later than five years after the date of enactment  
25 of this Act, the Secretary of Health and Human Services



1 shall, in consultation with the Food and Drug Administra-  
2 tion, Centers for Disease Control and Prevention and  
3 other appropriate agencies, submit to the Committee on  
4 Energy and Commerce of the House of Representatives  
5 and the Committee on Health, Education, Labor, and  
6 Pensions of the Senate a report that contains the fol-  
7 lowing:

8           (1)(A) The number of initial designations of  
9           drugs as qualified infectious disease products under  
10          section 505E of the Federal Food, Drug, and Cos-  
11          metic Act;

12          (B) the number of qualified infectious disease  
13          products approved under this program; and

14          (C) whether such products address the need for  
15          antibacterial and antifungal drugs to treat serious  
16          and life-threatening infections.

17          (2) Recommendations—

18                (A) based on the information in paragraph  
19                (1) and any other relevant data, on any changes  
20                that should be made to the list of pathogens  
21                that are defined as qualifying pathogens under  
22                section 505E(f)(2) of the Federal Food, Drug,  
23                and Cosmetic Act, as added by section 831; and

24                (B) on whether any additional program  
25                (such as the development of public-private col-

laborations to advance antibacterial drug innovation) or changes to the incentives under this subtitle may be needed to promote the development of antibacterial drugs.

(3) An examination of—

(A) the adoption of programs to measure the use of antibacterial drugs in health care settings; and

(B) the implementation and effectiveness of antimicrobial stewardship protocols across all health care settings.

(4) Any recommendations for ways to encourage further development and establishment of stewardship programs.

**SEC. 835. GUIDANCE ON PATHOGEN-FOCUSED ANTIBACTERIAL DRUG DEVELOPMENT.**

(a) DRAFT GUIDANCE.—Not later than June 30, 2013, in order to facilitate the development of antibacterial drugs for serious or life-threatening bacterial infections, particularly in areas of unmet need, the Secretary of Health and Human Services shall publish draft guidance that—

(1) specifies how preclinical and clinical data can be utilized to inform an efficient and streamlined pathogen-focused antibacterial drug develop-

1       ment program that meets the approval standards of  
2       the Food and Drug Administration; and

3           (2) provides advice on approaches for the devel-  
4       opment of antibacterial drugs that target a more  
5       limited spectrum of pathogens.

6       (b) FINAL GUIDANCE.—Not later than December 31,  
7       2014, after notice and opportunity for public comment on  
8       the draft guidance under subsection (a), the Secretary of  
9       Health and Human Services shall publish final guidance  
10      consistent with this section.

## 11      **Subtitle D—Accelerated Approval**

### 12      **SEC. 841. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS** 13                           **OR LIFE-THREATENING DISEASES OR CONDI-** 14                           **TIONS.**

15      (a) FINDINGS; SENSE OF CONGRESS.—

16           (1) FINDINGS.—The Congress finds as follows:

17                   (A) The Food and Drug Administration  
18                   (referred to in this subsection as the “FDA”)  
19                   serves a critical role in helping to assure that  
20                   new medicines are safe and effective. Regu-  
21                   latory innovation is 1 element of the Nation’s  
22                   strategy to address serious and life-threatening  
23                   diseases or conditions by promoting investment  
24                   in and development of innovative treatments for  
25                   unmet medical needs.

1 (B) During the 2 decades following the es-  
2 tablishment of the accelerated approval mecha-  
3 nism, advances in medical sciences, including  
4 genomics, molecular biology, and bioinformatics,  
5 have provided an unprecedented understanding  
6 of the underlying biological mechanism and  
7 pathogenesis of disease. A new generation of  
8 modern, targeted medicines is under develop-  
9 ment to treat serious and life-threatening dis-  
10 eases, some applying drug development strate-  
11 gies based on biomarkers or pharmacogenomics,  
12 predictive toxicology, clinical trial enrichment  
13 techniques, and novel clinical trial designs, such  
14 as adaptive clinical trials.

15 (C) As a result of these remarkable sci-  
16 entific and medical advances, the FDA should  
17 be encouraged to implement more broadly effec-  
18 tive processes for the expedited development  
19 and review of innovative new medicines in-  
20 tended to address unmet medical needs for seri-  
21 ous or life-threatening diseases or conditions,  
22 including those for rare diseases or conditions,  
23 using a broad range of surrogate or clinical  
24 endpoints and modern scientific tools earlier in  
25 the drug development cycle when appropriate.

1           This may result in fewer, smaller, or shorter  
2           clinical trials for the intended patient popu-  
3           lation or targeted subpopulation without com-  
4           promising or altering the high standards of the  
5           FDA for the approval of drugs.

6           (D) Patients benefit from expedited access  
7           to safe and effective innovative therapies to  
8           treat unmet medical needs for serious or life-  
9           threatening diseases or conditions.

10          (E) For these reasons, the statutory au-  
11          thority in effect on the day before the date of  
12          enactment of this Act governing expedited ap-  
13          proval of drugs for serious or life-threatening  
14          diseases or conditions should be amended in  
15          order to enhance the authority of the FDA to  
16          consider appropriate scientific data, methods,  
17          and tools, and to expedite development and ac-  
18          cess to novel treatments for patients with a  
19          broad range of serious or life-threatening dis-  
20          eases or conditions.

21          (2) SENSE OF CONGRESS.—It is the sense of  
22          the Congress that the FDA should apply the acceler-  
23          ated approval and fast track provisions set forth in  
24          section 506 of the Federal Food, Drug, and Cos-  
25          metic Act (21 U.S.C. 356), as amended by this sec-

1       tion, to help expedite the development and avail-  
2       ability to patients of treatments for serious or life-  
3       threatening diseases or conditions while maintaining  
4       safety and effectiveness standards for such treat-  
5       ments.

6       (b) EXPEDITED APPROVAL.—Section 506 (21 U.S.C.  
7       356) is amended to read as follows:

8       **“SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS**  
9                               **OR LIFE-THREATENING DISEASES OR CONDI-**  
10                              **TIONS.**

11       “(a) DESIGNATION OF DRUG AS A FAST TRACK  
12       PRODUCT.—

13               “(1) IN GENERAL.—The Secretary shall, at the  
14       request of the sponsor of a new drug, facilitate the  
15       development and expedite the review of such drug if  
16       it is intended, whether alone or in combination with  
17       one or more other drugs, for the treatment of a seri-  
18       ous or life-threatening disease or condition, and it  
19       demonstrates the potential to address unmet medical  
20       needs for such a disease or condition. (In this sec-  
21       tion, such a drug is referred to as a ‘fast track prod-  
22       uct’.)

23               “(2) REQUEST FOR DESIGNATION.—The spon-  
24       sor of a new drug may request the Secretary to des-  
25       ignate the drug as a fast track product. A request

1 for the designation may be made concurrently with,  
2 or at any time after, submission of an application  
3 for the investigation of the drug under section 505(i)  
4 of this Act or section 351(a)(3) of the Public Health  
5 Service Act.

6 “(3) DESIGNATION.—Within 60 calendar days  
7 after the receipt of a request under paragraph (2),  
8 the Secretary shall determine whether the drug that  
9 is the subject of the request meets the criteria de-  
10 scribed in paragraph (1). If the Secretary finds that  
11 the drug meets the criteria, the Secretary shall des-  
12 ignate the drug as a fast track product and shall  
13 take such actions as are appropriate to expedite the  
14 development and review of the application for ap-  
15 proval of such product.

16 “(b) ACCELERATED APPROVAL OF A DRUG FOR A  
17 SERIOUS OR LIFE-THREATENING DISEASE OR CONDI-  
18 TION, INCLUDING A FAST TRACK PRODUCT.—

19 “(1) IN GENERAL.—The Secretary may approve  
20 an application for approval of a product for a seri-  
21 ous or life-threatening disease or condition, including  
22 a fast track product, under section 505(c) of this  
23 Act or section 351(a) of the Public Health Service  
24 Act upon making a determination that the product  
25 has an effect on—

1           “(A) a surrogate endpoint that is reason-  
2           ably likely to predict clinical benefit; or

3           “(B) a clinical endpoint that can be meas-  
4           ured earlier than irreversible morbidity or mor-  
5           tality, that is reasonably likely to predict an ef-  
6           fect on irreversible morbidity or mortality or  
7           other clinical benefit,

8           taking into account the severity or rarity of the dis-  
9           ease or condition and the availability of alternative  
10          treatments. The evidence to support that an end-  
11          point is reasonably likely to predict clinical benefit  
12          may include epidemiological, pathophysiologic, phar-  
13          macologic, therapeutic or other evidence developed  
14          using, for example, biomarkers, or other scientific  
15          methods or tools.

16          “(2) LIMITATION.—Approval of a product  
17          under this subsection may, as determined by the  
18          Secretary, be subject to the following require-  
19          ments—

20               “(A) that the sponsor conduct appropriate  
21               post-approval studies to verify and describe the  
22               predicted effect of the product on irreversible  
23               morbidity or mortality or other clinical benefit;  
24               and



1           “(B) that the sponsor submit copies of all  
2           promotional materials related to the product, at  
3           least 30 days prior to dissemination of the ma-  
4           terials—

5                   “(i) during the preapproval review pe-  
6                   riod; and

7                   “(ii) following approval, for a period  
8                   that the Secretary determines to be appro-  
9                   priate.

10           “(3)   EXPEDITED   WITHDRAWAL   OF   AP-  
11           PROVAL.—The Secretary may withdraw approval of  
12           a product approved pursuant to this subsection  
13           using expedited procedures (as prescribed by the  
14           Secretary in regulations, which shall include an op-  
15           portunity for an informal hearing) if—

16                   “(A) the sponsor fails to conduct any re-  
17                   quired post-approval study of the product with  
18                   due diligence;

19                   “(B) a study required to verify and de-  
20                   scribe the predicted effect on irreversible mor-  
21                   bidity or mortality or other clinical benefit of  
22                   the product fails to verify and describe such ef-  
23                   fect or benefit;

1           “(C) other evidence demonstrates that the  
2           product is not safe or effective under the condi-  
3           tions of use; or

4           “(D) the sponsor disseminates false or  
5           misleading promotional materials with respect  
6           to the product.

7           “(c) REVIEW OF INCOMPLETE APPLICATIONS FOR  
8   APPROVAL OF A FAST TRACK PRODUCT.—

9           “(1) IN GENERAL.—If the Secretary deter-  
10          mines, after preliminary evaluation of clinical data  
11          submitted by the sponsor, that a fast track product  
12          may be effective, the Secretary shall evaluate for fil-  
13          ing, and may commence review of portions of, an ap-  
14          plication for the approval of the product before the  
15          sponsor submits a complete application. The Sec-  
16          retary shall commence such review only if the appli-  
17          cant—

18               “(A) provides a schedule for submission of  
19               information necessary to make the application  
20               complete; and

21               “(B) pays any fee that may be required  
22               under section 736.

23           “(2) EXCEPTION.—Any time period for review  
24          of human drug applications that has been agreed to  
25          by the Secretary and that has been set forth in goals

1 identified in letters of the Secretary (relating to the  
2 use of fees collected under section 736 to expedite  
3 the drug development process and the review of  
4 human drug applications) shall not apply to an ap-  
5 plication submitted under paragraph (1) until the  
6 date on which the application is complete.

7 “(d) AWARENESS EFFORTS.—The Secretary shall—  
8 “(1) develop and disseminate to physicians, pa-  
9 tient organizations, pharmaceutical and bio-  
10 technology companies, and other appropriate persons  
11 a description of the provisions of this section appli-  
12 cable to accelerated approval and fast track prod-  
13 ucts; and

14 “(2) establish a program to encourage the de-  
15 velopment of surrogate and clinical endpoints, in-  
16 cluding biomarkers, and other scientific methods and  
17 tools that can assist the Secretary in determining  
18 whether the evidence submitted in an application is  
19 reasonably likely to predict clinical benefit for seri-  
20 ous or life-threatening conditions for which there  
21 exist significant unmet medical needs.”.

22 **SEC. 842. GUIDANCE; AMENDED REGULATIONS.**

23 (a) INITIAL GUIDANCE.—Not later than one year  
24 after the date of enactment of this Act, the Secretary of  
25 Health and Human Services (in this subtitle referred to

1 as the “Secretary”) shall issue draft guidance to imple-  
2 ment the amendment made by section 841.

3 (b) FINAL GUIDANCE.—Not later than one year after  
4 the issuance of draft guidance under subsection (a), after  
5 an opportunity for public comment, the Secretary shall—

6 (1) issue final guidance to implement the  
7 amendment made by section 841; and

8 (2) amend the regulations governing accelerated  
9 approval in parts 314 and 601 of title 21, Code of  
10 Federal Regulations, as necessary to conform such  
11 regulations with the amendments made by section  
12 841.

13 (c) CONSIDERATIONS.—In developing the guidance  
14 under subsections (a) and (b)(1) and the amendments  
15 under subsection (b)(2), the Secretary shall consider—

16 (1) issues arising under the accelerated ap-  
17 proval and fast track processes under section 506 of  
18 the Federal Food, Drug, and Cosmetic Act (as  
19 amended by section 841) for drugs designated for a  
20 rare disease or condition under section 526 of the  
21 Federal, Food, Drug, and Cosmetic Act; and

22 (2) how to incorporate novel approaches to the  
23 review of surrogate endpoints based on patho-  
24 physiologic and pharmacologic evidence in such guid-  
25 ance, especially in instances where the low preva-

1        lence of a disease renders the existence or collection  
2        of other types of data unlikely or impractical.

3        (d) NO DELAY IN REVIEW OR APPROVAL.—The  
4        issuance (or non-issuance) of guidance or conforming reg-  
5        ulations implementing the amendments made by section  
6        841 shall not preclude the review of, or action on, a re-  
7        quest for designation or an application for approval sub-  
8        mitted pursuant to section 506 of the Federal Food, Drug,  
9        and Cosmetic Act, as amended by section 841.

10    **SEC. 843. INDEPENDENT REVIEW.**

11        (a) IN GENERAL.—The Secretary may, in conjunc-  
12        tion with other planned reviews of the new drug review  
13        process, contract with an independent entity with expertise  
14        in assessing the quality and efficiency of biopharma-  
15        ceutical development and regulatory review programs, to  
16        evaluate the Food and Drug Administration’s application  
17        of the processes described in section 506 of the Federal  
18        Food, Drug, and Cosmetic Act, as amended by section  
19        841, and the impact of such processes on the development  
20        and timely availability of innovative treatments for pa-  
21        tients suffering from serious or life-threatening conditions.

22        (b) CONSULTATION.—Any evaluation under sub-  
23        section (a) shall include consultation with regulated indus-  
24        tries, patient advocacy and disease research foundations,  
25        and relevant academic medical centers.

## Subtitle E—Critical Path Reauthorization

### SEC. 851. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.

Subsection (f) of section 566 (21 U.S.C. 360bbb–5) is amended to read as follows:

“(f) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated \$6,000,000 for each of fiscal years 2013 through 2017.”.

## Subtitle F—Miscellaneous

### SEC. 861. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.

Section 505(u)(4) (21 U.S.C. 355(u)(4)) is amended by striking “2012” and inserting “2017”.

### SEC. 862. EXTENSION OF PERIOD FOR FIRST APPLICANT TO OBTAIN TENTATIVE APPROVAL WITHOUT FORFEITING 180-DAY EXCLUSIVITY PERIOD.

(a) EXTENSION OF PERIOD.—

(1) IN GENERAL.—Subclause (IV) of section 505(j)(5)(D)(i) (21 U.S.C. 355(j)(5)(D)(i)) is amended to read as follows:

“(IV) FAILURE TO OBTAIN TENTATIVE APPROVAL.—The first appli-

1 cant fails to obtain tentative approval  
2 of the application within 45 months  
3 after the date on which—

4 “(aa) the application is filed  
5 and initially contains a certifi-  
6 cation described in paragraph  
7 (2)(A)(vii)(IV), or

8 “(bb) the application is  
9 amended to first contain such a  
10 certification,

11 unless the failure is caused by a  
12 change in or a review of the require-  
13 ments for approval of the application  
14 imposed after the date on which the  
15 application is so filed or amended.”.

16 (2) APPLICABILITY.—

17 (A) IN GENERAL.—Subject to subsection  
18 (b), the amendment made by paragraph (1) ap-  
19 plies—

20 (i) only with respect to an application  
21 that is filed under section 505(j) of the  
22 Federal Food, Drug, and Cosmetic Act (21  
23 U.S.C. 355(j)) on or after the day that is  
24 30 months prior to the date of the enact-  
25 ment of this Act; and

1 (ii) only if no certification under para-  
2 graph (2)(A)(vii)(IV) of such section  
3 505(j) was made before such day with re-  
4 spect to the listed drug (as such term is  
5 used in such section 505(j)).

6 (B) CERTAIN APPLICATIONS.—If an appli-  
7 cation was filed under section 505(j) of the  
8 Federal Food, Drug, and Cosmetic Act (21  
9 U.S.C. 355(j)) prior to the day specified in sub-  
10 paragraph (A)(i) and, on such day, contained a  
11 certification described in paragraph  
12 (2)(A)(vii)(IV), the application shall be subject  
13 to paragraph (5)(D)(i)(IV) of such section  
14 505(j) as in effect on the day before the date  
15 of the enactment of this Act.

16 (b) INCREMENTAL REDUCTION OF EXTENDED PE-  
17 RIOD.—

18 (1) PERIOD DURATION.—

19 (A) Effective on October 1, 2013, sub-  
20 clause (IV) of section 505(j)(5)(D)(i) (21  
21 U.S.C. 355(j)(5)(D)(i)), as amended by sub-  
22 section (a)(1) of this section, is amended by  
23 striking “45 months” and inserting “42  
24 months”.



1 (B) Effective on October 1, 2014, sub-  
2 clause (IV) of section 505(j)(5)(D)(i) (21  
3 U.S.C. 355(j)(5)(D)(i)), as amended by sub-  
4 paragraph (A) of this paragraph, is amended by  
5 striking “42 months” and inserting “39  
6 months”.

7 (C) Effective on October 1, 2015, sub-  
8 clause (IV) of section 505(j)(5)(D)(i) (21  
9 U.S.C. 355(j)(5)(D)(i)), as amended by sub-  
10 paragraph (B) of this paragraph, is amended by  
11 striking “39 months” and inserting “36  
12 months”.

13 (D) Effective on October 1, 2016, sub-  
14 clause (IV) of section 505(j)(5)(D)(i) (21  
15 U.S.C. 355(j)(5)(D)(i)), as amended by sub-  
16 paragraph (C) of this paragraph, is amended by  
17 striking “36 months” and inserting “33  
18 months”.

19 (E) Effective on October 1, 2017, sub-  
20 clause (IV) of section 505(j)(5)(D)(i) (21  
21 U.S.C. 355(j)(5)(D)(i)), as amended by sub-  
22 paragraph (D) of this paragraph, is amended  
23 by striking “33 months” and inserting “30  
24 months”.

25 (2) APPLICABILITY.—

1           (A) The amendments made by subpara-  
2           graphs (A), (B), (C), and (D) of paragraph (1)  
3           apply only with respect to an application under  
4           section 505(j) of the Federal Food, Drug, and  
5           Cosmetic Act (21 U.S.C. 355(j)) that—

6                   (i) is filed and initially contains a cer-  
7                   tification described in paragraph  
8                   (2)(A)(vii)(IV) during the period of one  
9                   fiscal year beginning on the effective date  
10                  of the respective amendment; or

11                  (ii) is amended to initially contain  
12                  such a certification during such period.

13           (B) The amendment made by paragraph  
14           (1)(E) applies only with respect to an applica-  
15           tion under section 505(j) of the Federal Food,  
16           Drug, and Cosmetic Act (21 U.S.C. 355(j))  
17           that—

18                   (i) is filed and initially contains a cer-  
19                   tification described in paragraph  
20                   (2)(A)(vii)(IV) on or after October 1,  
21                   2017; or

22                   (ii) is amended to initially contain  
23                   such a certification on or after October 1,  
24                   2017.

1 (c) CONFORMING AMENDMENT.—Subparagraph (G)  
 2 of section 505(q)(1) (21 U.S.C. 355(q)(1)) is amended—

3 (1) in the subparagraph heading, by striking  
 4 “30-MONTH PERIOD” and inserting “PERIOD”; and  
 5 (2) by striking “the 30-month period” and in-  
 6 serting “the period”.

7 **SEC. 863. FINAL AGENCY ACTION RELATING TO PETITIONS**  
 8 **AND CIVIL ACTIONS.**

9 Section 505(q) (21 U.S.C. 355(q)) is amended—

10 (1) in paragraph (1)(F), by striking “180  
 11 days” and inserting “150 days”; and

12 (2) in paragraph (2)(A)—

13 (A) in the subparagraph heading, by strik-  
 14 ing “180” and inserting “150”; and

15 (B) in clause (i), by striking “180-day”  
 16 and inserting “150-day”.

17 **SEC. 864. DEADLINE FOR DETERMINATION ON CERTAIN PE-**  
 18 **TITIONS.**

19 (a) IN GENERAL.—Section 505 (21 U.S.C. 355) is  
 20 amended by adding at the end the following:

21 “(w) DEADLINE FOR DETERMINATION ON CERTAIN  
 22 PETITIONS.—The Secretary shall issue a final, substantive  
 23 determination on a petition submitted pursuant to sub-  
 24 section (b) of section 314.161 of title 21, Code of Federal

1 Regulations (or any successor regulations), no later than  
2 270 days after the date the petition is submitted.”.

3 (b) APPLICATION.—The amendment made by sub-  
4 section (a) shall apply to any petition that is submitted  
5 pursuant to subsection (b) of section 314.161 of title 21,  
6 Code of Federal Regulations (or any successor regula-  
7 tions), on or after the date of enactment of this Act.

8 **SEC. 865. RARE PEDIATRIC DISEASE PRIORITY REVIEW**  
9 **VOUCHER INCENTIVE PROGRAM.**

10 Subchapter B of Chapter V (21 U.S.C. 360aa et seq.)  
11 is amended by adding at the end the following:

12 **“SEC. 529. PRIORITY REVIEW TO ENCOURAGE TREATMENTS**  
13 **FOR RARE PEDIATRIC DISEASES.**

14 “(a) DEFINITIONS.—In this section:

15 “(1) PRIORITY REVIEW.—The term ‘priority re-  
16 view’, with respect to a human drug application as  
17 defined in section 735(1), means review and action  
18 by the Secretary on such application not later than  
19 6 months after receipt by the Secretary of such ap-  
20 plication, as described in the Manual of Policies and  
21 Procedures of the Food and Drug Administration  
22 and goals identified in the letters described in sec-  
23 tion 101(b) of the Prescription Drug User Fee  
24 Amendments of 2012.

1           “(2) PRIORITY REVIEW VOUCHER.—The term  
2           ‘priority review voucher’ means a voucher issued by  
3           the Secretary to the sponsor of a rare pediatric dis-  
4           ease product application that entitles the holder of  
5           such voucher to priority review of a single human  
6           drug application submitted under section 505(b)(1)  
7           or section 351(a) of the Public Health Service Act  
8           after the date of approval of the rare pediatric dis-  
9           ease product application.

10           “(3) RARE PEDIATRIC DISEASE.—The term  
11           ‘rare pediatric disease’ means a disease that meets  
12           each of the following criteria:

13                   “(A) The disease primarily affects individ-  
14                   uals aged from birth to 18 years, including age  
15                   groups often called neonates, infants, children,  
16                   and adolescents.

17                   “(B) The disease is a rare disease or con-  
18                   dition, within the meaning of section 526.

19           “(4) RARE PEDIATRIC DISEASE PRODUCT AP-  
20           PLICATION.—The term ‘rare pediatric disease prod-  
21           uct application’ means a human drug application, as  
22           defined in section 735(1), that—

23                   “(A) is for a drug or biological product—

24                           “(i) that is for the prevention or  
25                           treatment of a rare pediatric disease;

1 “(ii) that contains no active ingredient  
2 (including any ester or salt of the active  
3 ingredient) that has been previously ap-  
4 proved in any other application under sec-  
5 tion 505(b)(1), 505(b)(2), or 505(j) of this  
6 Act or section 351(a) or 351(k) of the  
7 Public Health Service Act;

8 “(B) is submitted under section 505(b)(1)  
9 of this Act or section 351(a) of the Public  
10 Health Service Act;

11 “(C) the Secretary deems eligible for pri-  
12 ority review;

13 “(D) that relies on clinical data derived  
14 from studies examining a pediatric population  
15 and dosages of the drug intended for that popu-  
16 lation;

17 “(E) that does not seek approval for an  
18 adult indication in the original rare pediatric  
19 disease product application; and

20 “(F) is approved after the date of the en-  
21 actment of the Prescription Drug User Fee  
22 Amendments of 2012.

23 “(b) PRIORITY REVIEW VOUCHER.—

24 “(1) IN GENERAL.—The Secretary shall award  
25 a priority review voucher to the sponsor of a rare pe-

1       diatric disease product application upon approval by  
2       the Secretary of such rare pediatric disease product  
3       application.

4           “(2) TRANSFERABILITY.—

5               “(A) IN GENERAL.—The sponsor of a rare  
6       pediatric disease product application that re-  
7       ceives a priority review voucher under this sec-  
8       tion may transfer (including by sale) the enti-  
9       tlement to such voucher. There is no limit on  
10      the number of times a priority review voucher  
11      may be transferred before such voucher is used.

12           “(B) NOTIFICATION OF TRANSFER.—Each  
13      person to whom a voucher is transferred shall  
14      notify the Secretary of such change in owner-  
15      ship of the voucher not later than 30 days after  
16      such transfer.

17           “(3) LIMITATION.—A sponsor of a rare pedi-  
18      atric disease product application may not receive a  
19      priority review voucher under this section if the rare  
20      pediatric disease product application was submitted  
21      to the Secretary prior to the date that is 90 days  
22      after the date of enactment of the Prescription Drug  
23      User Fee Amendments of 2012.

24           “(4) NOTIFICATION.—

1           “(A) IN GENERAL.—The sponsor of a  
2           human drug application shall notify the Sec-  
3           retary not later than 90 days prior to submis-  
4           sion of the human drug application that is the  
5           subject of a priority review voucher of an intent  
6           to submit the human drug application, includ-  
7           ing the date on which the sponsor intends to  
8           submit the application. Such notification shall  
9           be a legally binding commitment to pay for the  
10          user fee to be assessed in accordance with this  
11          section.

12          “(B) TRANSFER AFTER NOTICE.—The  
13          sponsor of a human drug application that pro-  
14          vides notification of the intent of such sponsor  
15          to use the voucher for the human drug applica-  
16          tion under subparagraph (A) may transfer the  
17          voucher after such notification is provided, if  
18          such sponsor has not yet submitted the human  
19          drug application described in the notification.

20          “(5) TERMINATION OF AUTHORITY.—The Sec-  
21          retary may not award any priority review vouchers  
22          under paragraph (1) after the last day of the 1-year  
23          period that begins on the date that the Secretary  
24          awards the third rare pediatric disease priority  
25          voucher under this section.



1 “(c) PRIORITY REVIEW USER FEE.—

2 “(1) IN GENERAL.—The Secretary shall estab-  
3 lish a user fee program under which a sponsor of a  
4 human drug application that is the subject of a pri-  
5 ority review voucher shall pay to the Secretary a fee  
6 determined under paragraph (2). Such fee shall be  
7 in addition to any fee required to be submitted by  
8 the sponsor under chapter VII.

9 “(2) FEE AMOUNT.—The amount of the pri-  
10 ority review user fee shall be determined each fiscal  
11 year by the Secretary, based on the difference be-  
12 tween—

13 “(A) the average cost incurred by the Food  
14 and Drug Administration in the review of a  
15 human drug application subject to priority re-  
16 view in the previous fiscal year; and

17 “(B) the average cost incurred by the  
18 Food and Drug Administration in the review of  
19 a human drug application that is not subject to  
20 priority review in the previous fiscal year.

21 “(3) ANNUAL FEE SETTING.—The Secretary  
22 shall establish, before the beginning of each fiscal  
23 year beginning after September 30, 2012, the  
24 amount of the priority review user fee for that fiscal  
25 year.

1 “(4) PAYMENT.—

2 “(A) IN GENERAL.—The priority review  
3 user fee required by this subsection shall be due  
4 upon the notification by a sponsor of the intent  
5 of such sponsor to use the voucher, as specified  
6 in subsection (b)(4)(A). All other user fees as-  
7 sociated with the human drug application shall  
8 be due as required by the Secretary or under  
9 applicable law.

10 “(B) COMPLETE APPLICATION.—An appli-  
11 cation described under subparagraph (A) for  
12 which the sponsor requests the use of a priority  
13 review voucher shall be considered incomplete if  
14 the fee required by this subsection and all other  
15 applicable user fees are not paid in accordance  
16 with the Secretary’s procedures for paying such  
17 fees.

18 “(C) NO WAIVERS, EXEMPTIONS, REDUC-  
19 TIONS, OR REFUNDS.—The Secretary may not  
20 grant a waiver, exemption, reduction, or refund  
21 of any fees due and payable under this section.

22 “(5) OFFSETTING COLLECTIONS.—Fees col-  
23 lected pursuant to this subsection for any fiscal  
24 year—

1           “(A) shall be deposited and credited as off-  
2           setting collections to the account providing ap-  
3           propriations to the Food and Drug Administra-  
4           tion; and

5           “(B) shall not be collected for any fiscal  
6           year except to the extent provided in advance in  
7           appropriation Acts.

8           “(d) DESIGNATION PROCESS.—

9           “(1) IN GENERAL.—Upon the request of the  
10          manufacturer or the sponsor of a new drug, the Sec-  
11          retary may designate—

12           “(A) the new drug as a drug for a rare pe-  
13          diatric disease; and

14           “(B) the application for the new drug as a  
15          rare pediatric disease product application.

16          “(2) REQUEST FOR DESIGNATION.—The re-  
17          quest for a designation under paragraph (1), shall  
18          be made at the same time a request for designation  
19          of orphan disease status under section 526 or fast-  
20          track designation under section 506 is made. Re-  
21          questing designation under this subsection is not a  
22          prerequisite to receiving a priority review voucher  
23          under this section.

24          “(3) DETERMINATION BY SECRETARY.—Not  
25          later than 60 days after a request is submitted

1 under paragraph (1), the Secretary shall determine  
2 whether—

3 “(A) the disease or condition that is the  
4 subject of such request is a rare pediatric dis-  
5 ease; and

6 “(B) the application for the new drug is a  
7 rare pediatric disease product application.

8 “(e) MARKETING OF RARE PEDIATRIC DISEASE  
9 PRODUCTS.—

10 “(1) IN GENERAL.—The Secretary shall deem a  
11 rare pediatric disease product application incomplete  
12 if such application does not contain a description of  
13 the plan of the sponsor of such application to mar-  
14 ket the product in the United States.

15 “(2) REVOCATION.—The Secretary may revoke  
16 any priority review voucher awarded under sub-  
17 section (b) if the rare pediatric disease product for  
18 which such voucher was awarded is not marketed in  
19 the United States within the 365 day period begin-  
20 ning on the date of the approval of such drug under  
21 section 505 of this Act or section 351 of the Public  
22 Health Service Act.

23 “(3) POSTAPPROVAL PRODUCTION REPORT.—  
24 The sponsor of an approved rare pediatric disease  
25 product shall submit a report to the Secretary not

1 later than 5 years after the approval of the applica-  
2 ble rare pediatric disease product application. Such  
3 report shall provide the following information, with  
4 respect to each of the first 4 years after approval of  
5 such product:

6 “(A) The estimated population in the  
7 United States suffering from the rare pediatric  
8 disease.

9 “(B) The estimated demand in the United  
10 States for such rare pediatric disease product.

11 “(C) The actual amount of such rare pedi-  
12 atric disease product distributed in the United  
13 States.

14 “(f) NOTICE AND REPORT.—

15 “(1) NOTICE OF ISSUANCE OF VOUCHER AND  
16 APPROVAL OF PRODUCTS UNDER VOUCHER.—The  
17 Secretary shall publish a notice in the Federal Reg-  
18 ister and on the Web site of the Food and Drug Ad-  
19 ministration not later than 30 days after the occur-  
20 rence of each of the following:

21 “(A) The Secretary issues a priority review  
22 voucher under this section.

23 “(B) The Secretary approves a drug pur-  
24 suant to an application submitted under section  
25 505(b) of this Act or section 351(a) of the Pub-

1           lic Health Service Act for which the sponsor of  
2           the application used a priority review voucher  
3           under this section.

4           “(2) REPORT.—If, after the last day of the 1-  
5           year period that begins on the date that the Sec-  
6           retary awards the third rare pediatric disease pri-  
7           ority voucher under this section, a sponsor of an ap-  
8           plication submitted under section 505(b) of this Act  
9           or section 351(a) of the Public Health Service Act  
10          for a drug uses a priority review voucher under this  
11          section for such application, the Secretary shall sub-  
12          mit to the Committee on Energy and Commerce of  
13          the House of Representatives and the Committee on  
14          Health, Education, Labor, and Pensions of the Sen-  
15          ate a document—

16               “(A) notifying such Committees of the use  
17               of such voucher; and

18               “(B) identifying the drug for which such  
19               priority review voucher is used.

20          “(g) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing  
21          in this section precludes a sponsor who seeks a priority  
22          review voucher under this section from participating in  
23          any other incentive program, including under this Act.

24          “(h) RELATION TO OTHER PROVISIONS.—The provi-  
25          sions of this section shall supplement, not supplant, any

1 other provisions of this Act or the Public Health Service  
2 Act that encourage the development of drugs for tropical  
3 diseases and rare pediatric diseases.

4 “(i) GAO STUDY AND REPORT.—

5 “(1) STUDY.—

6 “(A) IN GENERAL.—Beginning on the date  
7 that the Secretary awards the third rare pedi-  
8 atric disease priority voucher under this section,  
9 the Comptroller General of the United States  
10 shall conduct a study of the effectiveness of  
11 awarding rare pediatric disease priority vouch-  
12 ers under this section in the development of on  
13 human drug products that treat or prevent such  
14 diseases.

15 “(B) CONTENTS OF STUDY.—In con-  
16 ducting the study under subparagraph (A), the  
17 Comptroller General shall examine the fol-  
18 lowing:

19 “(i) The indications for which each  
20 rare disease product for which a priority  
21 review voucher was awarded was approved  
22 under section 505 or section 351 of the  
23 Public Health Service Act.

24 “(ii) Whether, and to what extent, an  
25 unmet need related to the treatment or

1 prevention of a rare pediatric disease was  
2 met through the approval of such a rare  
3 disease product.

4 “(iii) The value of the priority review  
5 voucher if transferred.

6 “(iv) Identification of each drug for  
7 which a priority review voucher was used.

8 “(v) The length of the period of time  
9 between the date on which a priority re-  
10 view voucher was awarded and the date on  
11 which it was used.

12 “(2) REPORT.—Not later than 1 year after the  
13 date under paragraph (1)(A), the Comptroller Gen-  
14 eral shall submit to the Committee on Energy and  
15 Commerce of the House of Representatives and the  
16 Committee on Health, Education, Labor, and Pen-  
17 sions of the Senate, a report containing the results  
18 of the study under paragraph (1).”.

19 **SEC. 866. COMBATING PRESCRIPTION DRUG ABUSE.**

20 (a) IN GENERAL.—To combat the significant rise in  
21 prescription drug abuse and the consequences of such  
22 abuse, the Secretary of Health and Human Services (re-  
23 ferred to in this section as the “Secretary”), acting  
24 through the Commissioner of Food and Drugs (referred  
25 to in this section as the “Commissioner”) and in coordina-



1 tion with other Federal agencies, as appropriate, shall re-  
2 view current Federal initiatives and identify gaps and op-  
3 portunities with respect to ensuring the safe use of pre-  
4 scription drugs with the potential for abuse.

5 (b) REPORT.—Not later than 1 year after the date  
6 of enactment of this Act, the Secretary shall issue a report  
7 to Congress on the findings of the review under subsection  
8 (a). Such report shall include recommendations on—

9 (1) how best to leverage and build upon existing  
10 Federal and federally funded data sources, such as  
11 prescription drug monitoring program data and the  
12 sentinel initiative of the Food and Drug Administra-  
13 tion under section 505(k)(3) of the Federal Food,  
14 Drug, and Cosmetic Act (21 U.S.C. 351(k)(3)), as  
15 it relates to collection of information relevant to ad-  
16 verse events, patient safety, and patient outcomes, to  
17 create a centralized data clearinghouse and early  
18 warning tool;

19 (2) how best to develop and disseminate widely  
20 best practices models and suggested standard re-  
21 quirements to States for achieving greater interoper-  
22 ability and effectiveness of prescription drug moni-  
23 toring programs, especially with respect to producing  
24 standardized data on adverse events, patient safety,  
25 and patient outcomes; and

1           (3) how best to develop provider and patient  
2           education tools and a strategy to widely disseminate  
3           such tools and assess the efficacy of such tools.

4           (c) **GUIDANCE ON TAMPER-DETERRENT PROD-**  
5 **UCTS.**—Not later than 6 months after the date of enact-  
6 ment of this Act, the Secretary, acting through the Com-  
7 missioner, shall promulgate guidance on the development  
8 of tamper-deterrent drug products.

9 **SEC. 867. ASSESSMENT AND MODIFICATION OF REMS.**

10          (a) **ASSESSMENT AND MODIFICATION OF APPROVED**  
11 **STRATEGY.**—Section 505–1(g) (21 U.S.C. 355–1(g)) is  
12 amended—

13               (1) in paragraph (1), by striking “, and propose  
14               a modification to,”;

15               (2) in paragraph (2)—

16                       (A) in the matter before subparagraph  
17               (A)—

18                               (i) by striking “, subject to paragraph  
19                               (5),”; and

20                               (ii) by striking “, and may propose a  
21                               modification to,”;

22                       (B) in subparagraph (C), by striking “new  
23               safety or effectiveness information indicates  
24               that” and all that follows and inserting the fol-  
25               lowing: “an assessment is needed to evaluate

1           whether the approved strategy should be modi-  
2           fied to—

3                   “(i) ensure the benefits of the drug  
4                   outweigh the risks of the drug; or

5                   “(ii) minimize the burden on the  
6                   health care delivery system of complying  
7                   with the strategy.”; and

8                   (C) by striking subparagraph (D);

9           (3) in paragraph (3), by striking “for a drug  
10          shall include—” and all that follows and inserting  
11          the following “for a drug shall include, with respect  
12          to each goal included in the strategy, an assessment  
13          of the extent to which the approved strategy, includ-  
14          ing each element of the strategy, is meeting the goal  
15          or whether 1 or more such goals or such elements  
16          should be modified.”; and

17          (4) by amending paragraph (4) to read as fol-  
18          lows:

19               “(4) MODIFICATION.—

20                   “(A) ON INITIATIVE OF RESPONSIBLE  
21                   PERSON.—After the approval of a risk evalua-  
22                   tion and mitigation strategy by the Secretary,  
23                   the responsible person may, at any time, submit  
24                   to the Secretary a proposal to modify the ap-  
25                   proved strategy. Such proposal may propose the

1 addition, modification, or removal of any goal  
2 or element of the approved strategy and shall  
3 include an adequate rationale to support such  
4 proposed addition, modification, or removal of  
5 any goal or element of the strategy.

6 “(B) ON INITIATIVE OF SECRETARY.—  
7 After the approval of a risk evaluation and  
8 mitigation strategy by the Secretary, the Sec-  
9 retary may, at any time, require a responsible  
10 person to submit a proposed modification to the  
11 strategy within 120 days or within such reason-  
12 able time as the Secretary specifies, if the Sec-  
13 retary, in consultation with the offices described  
14 in subsection (c)(2), determines that 1 or more  
15 goals or elements should be added, modified, or  
16 removed from the approved strategy to—

17 “(i) ensure the benefits of the drug  
18 outweigh the risks of the drug; or

19 “(ii) minimize the burden on the  
20 health care delivery system of complying  
21 with the strategy.”.

22 (b) REVIEW OF PROPOSED STRATEGIES; REVIEW OF  
23 ASSESSMENTS AND MODIFICATIONS OF APPROVED  
24 STRATEGIES.—Section 505–1(h) (21 U.S.C. 355–1(h)) is  
25 amended—

1           (1) in the subsection heading by inserting “AND  
2       MODIFICATIONS” after “REVIEW OF ASSESS-  
3       MENTS”;

4           (2) in paragraph (1)—

5               (A) by inserting “and proposed modifica-  
6       tion to” after “under subsection (a) and each  
7       assessment of”; and

8               (B) by inserting “, and, if necessary,  
9       promptly initiate discussions with the respon-  
10      sible person about such proposed strategy, as-  
11      sessment, or modification” after “subsection  
12      (g)”;

13          (3) by striking paragraph (2);

14          (4) by redesignating paragraphs (3) through  
15      (9) as paragraphs (2) through (8), respectively;

16          (5) in paragraph (2), as redesignated by para-  
17      graph (4)—

18               (A) by amending subparagraph (A) to read  
19      as follows:

20                   “(A) IN GENERAL.—

21                       “(i) TIMEFRAME.—Unless the dispute  
22                      resolution process described under para-  
23                      graph (3) or (4) applies, and, except as  
24                      provided in clause (ii) or clause (iii) below,  
25                      the Secretary, in consultation with the of-

1           fices described in subsection (c)(2), shall  
2           review and act on the proposed risk evalua-  
3           tion and mitigation strategy for a drug or  
4           any proposed modification to any required  
5           strategy within 180 days of receipt of the  
6           proposed strategy or modification.

7           “(ii) MINOR MODIFICATIONS.—The  
8           Secretary shall review and act on a pro-  
9           posed minor modification, as defined by  
10          the Secretary in guidance, within 60 days  
11          of receipt of such modification.

12          “(iii) REMS MODIFICATION DUE TO  
13          SAFETY LABEL CHANGES.—Not later than  
14          60 days after the Secretary receives a pro-  
15          posed modification to an approved risk  
16          evaluation and mitigation strategy to con-  
17          form the strategy to approved safety label  
18          changes, including safety labeling changes  
19          initiated by the sponsor in accordance with  
20          FDA regulatory requirements, or to a safe-  
21          ty label change that the Secretary has di-  
22          rected the holder of the application to  
23          make pursuant to section 505(o)(4), the  
24          Secretary shall review and act on such pro-

posed modification to the approved strategy.

“(iv) GUIDANCE.—The Secretary shall establish, through guidance, that responsible persons may implement certain modifications to an approved risk evaluation and mitigation strategy following notification to the Secretary.”; and

(B) by amending subparagraph (C) to read as follows:

“(C) PUBLIC AVAILABILITY.—Upon acting on a proposed risk evaluation and mitigation strategy or proposed modification to a risk evaluation and mitigation strategy under subparagraph (A), the Secretary shall make publicly available an action letter describing the actions taken by the Secretary under such subparagraph (A).”.

(6) in paragraph (4), as redesignated by paragraph (4)—

(A) in subparagraph (A)(i)—

(i) by striking “Not earlier than 15 days, and not later than 35 days, after discussions under paragraph (2) have begun, the” and inserting “The”; and

1 (ii) by inserting “, after the sponsor is  
2 required to make a submission under sub-  
3 section (a)(2) or (g),” before “request in  
4 writing”; and

5 (B) in subparagraph (I)—

6 (i) by striking clauses (i) and (ii); and

7 (ii) by striking “if the Secretary—”  
8 and inserting “if the Secretary has com-  
9 plied with the timing requirements of  
10 scheduling review by the Drug Safety  
11 Oversight Board, providing a written rec-  
12 ommendation, and issuing an action letter  
13 under subparagraphs (B), (F), and (G),  
14 respectively.”;

15 (7) in paragraph (5), as redesignated by para-  
16 graph (4)—

17 (A) in subparagraph (A), by striking “any  
18 of subparagraph (B) through (D)” and insert-  
19 ing “subparagraph (B) or (C)”; and

20 (B) in subparagraph (C), by striking  
21 “paragraph (4) or (5)” and inserting “para-  
22 graph (3) or (4)”; and

23 (8) in paragraph (8), as redesignated by para-  
24 graph (4), by striking “paragraphs (7) and (8)” and  
25 inserting “paragraphs (6) and (7).”.



1 (c) GUIDANCE.—Not later than 1 year after the date  
2 of enactment of this Act, the Secretary of Health and  
3 Human Services shall issue guidance that, for purposes  
4 of section 505–1(h)(2)(A) of the Federal Food, Drug, and  
5 Cosmetic Act (21 U.S.C. 355–1(h)(2)(A)), describes the  
6 types of modifications to approved risk evaluation and  
7 mitigation strategies that shall be considered to be minor  
8 modifications of such strategies.

9 **SEC. 868. CONSULTATION WITH EXTERNAL EXPERTS ON**  
10 **RARE DISEASES, TARGETED THERAPIES, AND**  
11 **GENETIC TARGETING OF TREATMENTS.**

12 Subchapter E of chapter V (21 U.S.C. 360bbb et  
13 seq.) is amended by adding at the end the following:

14 **“SEC. 568. CONSULTATION WITH EXTERNAL EXPERTS ON**  
15 **RARE DISEASES, TARGETED THERAPIES, AND**  
16 **GENETIC TARGETING OF TREATMENTS.**

17 “(a) IN GENERAL.—For the purpose of promoting  
18 the efficiency of and informing the review by the Food  
19 and Drug Administration of new drugs and biological  
20 products for rare diseases and drugs and biological prod-  
21 ucts that are genetically targeted, the following shall  
22 apply:

23 “(1) CONSULTATION WITH STAKEHOLDERS.—  
24 Consistent with sections X.C and IX.E.4 of the  
25 PDUFA Reauthorization Performance Goals and

1 Procedures Fiscal Years 2013 through 2017, as ref-  
2 erenced in the letters described in section 101(b) of  
3 the Prescription Drug User Fee Amendments of  
4 2012, the Secretary shall ensure that opportunities  
5 exist, at a time the Secretary determines appro-  
6 priate, for consultations with stakeholders on the  
7 topics described in subsection (b).

8 “(2) CONSULTATION WITH EXTERNAL EX-  
9 PERTS.—

10 “(A) IN GENERAL.—The Secretary shall  
11 develop and maintain a list of external experts  
12 who, because of their special expertise, are  
13 qualified to provide advice on rare disease  
14 issues, including topics described in subsection  
15 (c). The Secretary may, when appropriate to  
16 address a specific regulatory question, consult  
17 such external experts on issues related to the  
18 review of new drugs and biological products for  
19 rare diseases and drugs and biological products  
20 that are genetically targeted, including the top-  
21 ics described in subsection (b), when such con-  
22 sultation is necessary because the Secretary  
23 lacks the specific scientific, medical, or tech-  
24 nical expertise necessary for the performance of  
25 the Secretary’s regulatory responsibilities and

1 the necessary expertise can be provided by the  
2 external experts.

3 “(B) EXTERNAL EXPERTS.—For purposes  
4 of subparagraph (A), external experts are indi-  
5 viduals who possess scientific or medical train-  
6 ing that the Secretary lacks with respect to one  
7 or more rare diseases.

8 “(b) TOPICS FOR CONSULTATION.—Topics for con-  
9 sultation pursuant to this section may include—

10 “(1) rare diseases;

11 “(2) the severity of rare diseases;

12 “(3) the unmet medical need associated with  
13 rare diseases;

14 “(4) the willingness and ability of individuals  
15 with a rare disease to participate in clinical trials;

16 “(5) an assessment of the benefits and risks of  
17 therapies to treat rare diseases;

18 “(6) the general design of clinical trials for rare  
19 disease populations and subpopulations; and

20 “(7) the demographics and the clinical descrip-  
21 tion of patient populations.

22 “(c) CLASSIFICATION AS SPECIAL GOVERNMENT EM-  
23 PLOYEES.—The external experts who are consulted under  
24 this section may be considered special government employ-

1 ees, as defined under section 202 of title 18, United States  
2 Code.

3 “(d) PROTECTION OF CONFIDENTIAL INFORMATION  
4 AND TRADE SECRETS.—

5 “(1) RULE OF CONSTRUCTION.—Nothing in  
6 this section shall be construed to alter the protec-  
7 tions offered by laws, regulations, and policies gov-  
8 erning disclosure of confidential commercial or trade  
9 secret information, and any other information ex-  
10 empt from disclosure pursuant to section 552(b) of  
11 title 5, United States Code, as such provisions would  
12 be applied to consultation with individuals and orga-  
13 nizations prior to the date of enactment of this sec-  
14 tion.

15 “(2) CONSENT REQUIRED FOR DISCLOSURE.—  
16 The Secretary shall not disclose confidential com-  
17 mercial or trade secret information to an expert con-  
18 sulted under this section without the written consent  
19 of the sponsor unless the expert is a special govern-  
20 ment employee (as defined under section 202 of title  
21 18, United States Code) or the disclosure is other-  
22 wise authorized by law.

23 “(e) OTHER CONSULTATION.—Nothing in this sec-  
24 tion shall be construed to limit the ability of the Secretary

1 to consult with individuals and organizations as authorized  
2 prior to the date of enactment of this section.

3 “(f) NO RIGHT OR OBLIGATION.—

4 “(1) NO RIGHT TO CONSULTATION.—Nothing  
5 in this section shall be construed to create a legal  
6 right for a consultation on any matter or require the  
7 Secretary to meet with any particular expert or  
8 stakeholder.

9 “(2) NO ALTERING OF GOALS.—Nothing in this  
10 section shall be construed to alter agreed upon goals  
11 and procedures identified in the letters described in  
12 section 101(b) of the Prescription Drug User Fee  
13 Amendments of 2012.

14 “(3) NO CHANGE TO NUMBER OF REVIEW CY-  
15 CLES.—Nothing in this section is intended to in-  
16 crease the number of review cycles as in effect before  
17 the date of enactment of this section.

18 “(g) NO DELAY IN PRODUCT REVIEW.—Prior to a  
19 consultation with an external expert, as described in this  
20 section, relating to an investigational new drug application  
21 under section 505(i), a new drug application under section  
22 505(b), or a biologics license application under section 351  
23 of the Public Health Service Act, the Director of the Cen-  
24 ter for Drug Evaluation and Research or the Director of  
25 the Center for Biologics Evaluation and Research (or ap-

1 appropriate Division Director), as appropriate, shall deter-  
2 mine that—

3 “(1) such consultation will—

4 “(A) facilitate the Secretary’s ability to  
5 complete the Secretary’s review;

6 “(B) address outstanding deficiencies in  
7 the application; and

8 “(C) increase the likelihood of an approval  
9 decision in the current review cycle; or

10 “(2) the sponsor authorized such consultation.”.

11 **SEC. 869. BREAKTHROUGH THERAPIES.**

12 (a) IN GENERAL.—Section 506 (21 U.S.C. 356), as  
13 amended by section 841, is further amended—

14 (1) by redesignating subsection (d) as sub-  
15 section (f);

16 (2) by redesignating subsections (a) through (c)  
17 as subsections (b) through (d), respectively;

18 (3) by inserting before subsection (b), as so re-  
19 designated, the following:

20 “(a) DESIGNATION OF A DRUG AS A BREAKTHROUGH  
21 THERAPY.—

22 “(1) IN GENERAL.—The Secretary shall, at the  
23 request of the sponsor of a drug, expedite the devel-  
24 opment and review of such drug if the drug is in-  
25 tended, alone or in combination with 1 or more other

1 drugs, to treat a serious or life-threatening disease  
2 or condition and preliminary clinical evidence indi-  
3 cates that the drug may demonstrate substantial im-  
4 provement over existing therapies on 1 or more clini-  
5 cally significant endpoints, such as substantial treat-  
6 ment effects observed early in clinical development.  
7 (In this section, such a drug is referred to as a  
8 ‘breakthrough therapy’.)

9 “(2) REQUEST FOR DESIGNATION.—The spon-  
10 sor of a drug may request the Secretary to designate  
11 the drug as a breakthrough therapy. A request for  
12 the designation may be made concurrently with, or  
13 at any time after, the submission of an application  
14 for the investigation of the drug under section 505(i)  
15 or section 351(a)(3) of the Public Health Service  
16 Act.

17 “(3) DESIGNATION.—

18 “(A) IN GENERAL.—Not later than 60 cal-  
19 endar days after the receipt of a request under  
20 paragraph (2), the Secretary shall determine  
21 whether the drug that is the subject of the re-  
22 quest meets the criteria described in paragraph  
23 (1). If the Secretary finds that the drug meets  
24 the criteria, the Secretary shall designate the  
25 drug as a breakthrough therapy and shall take

1 such actions as are appropriate to expedite the  
2 development and review of the application for  
3 approval of such drug.

4 “(B) ACTIONS.—The actions to expedite  
5 the development and review of an application  
6 under subparagraph (A) may include, as appro-  
7 priate—

8 “(i) holding meetings with the sponsor  
9 and the review team throughout the devel-  
10 opment of the drug;

11 “(ii) providing timely advice to, and  
12 interactive communication with, the spon-  
13 sor regarding the development of the drug  
14 to ensure that the development program to  
15 gather the non-clinical and clinical data  
16 necessary for approval is as efficient as  
17 practicable;

18 “(iii) involving senior managers and  
19 experienced review staff, as appropriate, in  
20 a collaborative, cross-disciplinary review;

21 “(iv) assigning a cross-disciplinary  
22 project lead for the Food and Drug Ad-  
23 ministration review team to facilitate an  
24 efficient review of the development pro-  
25 gram and to serve as a scientific liaison be-



1           tween the review team and the sponsor;  
2           and

3           “(v) taking steps to ensure that the  
4           design of the clinical trials is as efficient as  
5           practicable, when scientifically appropriate,  
6           such as by minimizing the number of pa-  
7           tients exposed to a potentially less effica-  
8           cious treatment.”;

9           (4) in subsection (f)(1), as so redesignated, by  
10          striking “applicable to accelerated approval” and in-  
11          serting “applicable to breakthrough therapies, accel-  
12          erated approval, and”; and

13          (5) by adding at the end the following:

14          “(g) REPORT.—Beginning in fiscal year 2013, the  
15          Secretary shall annually prepare and submit to the Com-  
16          mittee on Health, Education, Labor, and Pensions of the  
17          Senate and the Committee on Energy and Commerce of  
18          the House of Representatives, and make publicly available,  
19          with respect to this section for the previous fiscal year—

20                 “(1) the number of drugs for which a sponsor  
21                 requested designation as a breakthrough therapy;

22                 “(2) the number of products designated as a  
23                 breakthrough therapy; and

1 “(3) for each product designated as a break-  
2 through therapy, a summary of the actions taken  
3 under subsection (a)(3).”.

4 (b) GUIDANCE; AMENDED REGULATIONS.—

5 (1) IN GENERAL.—

6 (A) GUIDANCE.—Not later than 18  
7 months after the date of enactment of this Act,  
8 the Secretary of Health and Human Services  
9 (referred to in this section as the “Secretary”)  
10 shall issue draft guidance on implementing the  
11 requirements with respect to breakthrough  
12 therapies, as set forth in section 506(a) of the  
13 Federal Food, Drug, and Cosmetic Act (21  
14 U.S.C. 356(a)), as amended by this section.  
15 The Secretary shall issue final guidance not  
16 later than 1 year after the close of the comment  
17 period for the draft guidance.

18 (B) AMENDED REGULATIONS.—

19 (i) IN GENERAL.—If the Secretary de-  
20 termines that it is necessary to amend the  
21 regulations under title 21, Code of Federal  
22 Regulations in order to implement the  
23 amendments made by this section to sec-  
24 tion 506(a) of the Federal Food, Drug,  
25 and Cosmetic Act, the Secretary shall

1 amend such regulations not later than 2  
2 years after the date of enactment of this  
3 Act.

4 (ii) PROCEDURE.—In amending regu-  
5 lations under clause (i), the Secretary  
6 shall—

7 (I) issue a notice of proposed  
8 rulemaking that includes the proposed  
9 regulation;

10 (II) provide a period of not less  
11 than 60 days for comments on the  
12 proposed regulation; and

13 (III) publish the final regulation  
14 not less than 30 days before the effec-  
15 tive date of the regulation.

16 (iii) RESTRICTIONS.—Notwithstanding  
17 any other provision of law, the Secretary  
18 shall promulgate regulations implementing  
19 the amendments made by section only as  
20 described in clause (ii).

21 (2) REQUIREMENTS.—Guidance issued under  
22 this section shall—

23 (A) specify the process and criteria by  
24 which the Secretary makes a designation under

1 section 506(a)(3) of the Federal Food, Drug,  
2 and Cosmetic Act; and

3 (B) specify the actions the Secretary shall  
4 take to expedite the development and review of  
5 a breakthrough therapy pursuant to such des-  
6 ignation under such section 506(a)(3), includ-  
7 ing updating good review management practices  
8 to reflect breakthrough therapies.

9 (c) INDEPENDENT REVIEW.—Not later than 3 years  
10 after the date of enactment of this Act, the Comptroller  
11 General of the United States, in consultation with appro-  
12 priate experts, shall assess the manner by which the Food  
13 and Drug Administration has applied the processes de-  
14 scribed in section 506(a) of the Federal Food, Drug, and  
15 Cosmetic Act, as amended by this section, and the impact  
16 of such processes on the development and timely avail-  
17 ability of innovative treatments for patients affected by se-  
18 rious or life-threatening conditions. Such assessment shall  
19 be made publicly available upon completion.

20 (d) CONFORMING AMENDMENTS.—Section 506B(e)  
21 (21 U.S.C. 356b) is amended by striking “section  
22 506(b)(2)(A)” each place such term appears and inserting  
23 “section 506(c)(2)(A)”.

1 **SEC. 870. GRANTS AND CONTRACTS FOR THE DEVELOP-**  
 2 **MENT OF ORPHAN DRUGS.**

3 (a) QUALIFIED TESTING DEFINITION.—Section  
 4 5(b)(1)(A)(ii) of the Orphan Drug Act (21 U.S.C.  
 5 360ee(b)(1)(A)(ii)) is amended by striking “after the date  
 6 such drug is designated under section 526 of such Act  
 7 and”.

8 (b) AUTHORIZATION OF APPROPRIATIONS.—Section  
 9 5(c) of the Orphan Drug Act (21 U.S.C. 360ee(c)) is  
 10 amended to read as follows:

11 “(c) AUTHORIZATION OF APPROPRIATIONS.—For  
 12 grants and contracts under subsection (a), there is author-  
 13 ized to be appropriated \$30,000,000 for each of fiscal  
 14 years 2013 through 2017.”.

15 **TITLE IX—DRUG SHORTAGES**

16 **SEC. 901. DISCONTINUANCE AND INTERRUPTIONS OF MAN-**  
 17 **UFACTURING OF CERTAIN DRUGS.**

18 (a) IN GENERAL.—Section 506C (21 U.S.C. 356c)  
 19 is amended to read as follows:

20 **“SEC. 506C. DISCONTINUANCE AND INTERRUPTIONS OF**  
 21 **MANUFACTURING OF CERTAIN DRUGS.**

22 “(a) IN GENERAL.—A manufacturer of a drug sub-  
 23 ject to section 503(b)(1)—

24 “(1) that is—

25 “(A) life-supporting;

26 “(B) life-sustaining; or

1                   “(C) intended for use in the prevention or  
2                   treatment of a debilitating disease or condition;  
3                   and

4                   “(2) that is not a radio pharmaceutical drug  
5                   product, a product derived from human plasma pro-  
6                   tein and their recombinant analogs, or any other  
7                   product as designated by the Secretary,  
8                   shall notify the Secretary of a discontinuance of the manu-  
9                   facture of the drug, or an interruption of the manufacture  
10                  of the drug that is likely to lead to a meaningful disruption  
11                  in the manufacturer’s supply of the drug, and the reason  
12                  for such discontinuance or interruption, in accordance  
13                  with subsection (b).

14                  “(b) TIMING.—A notice required by subsection (a)  
15                  shall be submitted to the Secretary—

16                         “(1) at least 6 months prior to the date of the  
17                         discontinuance or interruption; or

18                         “(2) if compliance with paragraph (1) is not  
19                         possible, as soon as practicable.

20                  “(c) DISTRIBUTION.—To the maximum extent prac-  
21                  ticable, the Secretary shall distribute information on the  
22                  discontinuation or interruption of the manufacture of the  
23                  drugs described in subsection (a) to appropriate organiza-  
24                  tions, including physician, health provider, and patient or-  
25                  ganizations, as described in section 506D.

1       “(d) CONFIDENTIALITY.—Nothing in this section  
2 shall be construed as authorizing the Secretary to disclose  
3 any information that is a trade secret or confidential infor-  
4 mation subject to section 552(b)(4) of title 5, United  
5 States Code, or section 1905 of title 18, United States  
6 Code.

7       “(e) COORDINATION WITH ATTORNEY GENERAL.—  
8 Not later than 30 days after the receipt of a notification  
9 described in subsection (a), the Secretary shall—

10           “(1) determine whether the notification pertains  
11 to a controlled substance subject to a production  
12 quota under section 306 of the Controlled Sub-  
13 stances Act; and

14           “(2) if necessary, as determined by the Sec-  
15 retary—

16               “(A) notify the Attorney General that the  
17 Secretary has received such a notification;

18               “(B) request that the Attorney General in-  
19 crease the aggregate and individual production  
20 quotas under section 306 of the Controlled Sub-  
21 stances Act applicable to such controlled sub-  
22 stance and any ingredient therein to a level the  
23 Secretary deems necessary to address a short-  
24 age of a controlled substance based on the best  
25 available market data; and

1           “(C) if the Attorney General determines  
2           that the level requested is not necessary to ad-  
3           dress a shortage of a controlled substance, the  
4           Attorney General shall provide to the Secretary  
5           a written response detailing the basis for the  
6           Attorney General’s determination.

7           The Secretary shall make the written response pro-  
8           vided under subparagraph (C) available to the public  
9           on the Web site of the Food and Drug Administra-  
10          tion.

11          “(f) FAILURE TO MEET REQUIREMENTS.—If a per-  
12         son fails to submit information required under subsection  
13         (a) in accordance with subsection (b)—

14                 “(1) the Secretary shall issue a letter to such  
15                 person informing such person of such failure;

16                 “(2) not later than 30 calendar days after the  
17                 issuance of a letter under paragraph (1), the person  
18                 who receives such letter shall submit to the Sec-  
19                 retary a written response to such letter setting forth  
20                 the basis for noncompliance and providing informa-  
21                 tion required under subsection (a); and

22                 “(3) not later than 45 calendar days after the  
23                 issuance of a letter under paragraph (1), the Sec-  
24                 retary shall make such letter and any response to  
25                 such letter under paragraph (2) available to the pub-



1       lic on the Web site of the Food and Drug Adminis-  
2       tration, with appropriate redactions made to protect  
3       information described in subsection (d), except that,  
4       if the Secretary determines that the letter under  
5       paragraph (1) was issued in error or, after review of  
6       such response, the person had a reasonable basis for  
7       not notifying as required under subsection (a), the  
8       requirements of this paragraph shall not apply.”.

9       (b) REGULATIONS.—

10           (1) IN GENERAL.—Not later than 18 months  
11       after the date of the enactment of this Act, the Sec-  
12       retary of Health and Human Services, after issuing  
13       a notice of proposed rule and holding a public hear-  
14       ing, shall promulgate final regulations that imple-  
15       ment the amendment made by subsection (a).

16           (2) CONTENTS.—Such regulations shall, for  
17       purposes of section 506C of the Federal Food,  
18       Drug, and Cosmetic Act (21 U.S.C. 356c)—

19           (A) define the terms “life-supporting”,  
20       “life-sustaining”, and “intended for use in the  
21       prevention or treatment of a debilitating disease  
22       or condition”; and

23           (B) define the term “interruption of the  
24       manufacture of the drug that is likely to lead  
25       to a meaningful disruption in the manufactur-

1           er’s supply of the drug” to mean a change in  
2           production that is highly likely to lead to more  
3           than a negligible reduction in the supply of the  
4           drug and affects the ability of the manufacturer  
5           to meet demand for such drug, but not to in-  
6           clude a change in production due to matters  
7           such as routine maintenance or insignificant  
8           changes in manufacturing so long as the manu-  
9           facturer expects to resume operations in a short  
10          period of time.

11 **SEC. 902. DRUG SHORTAGE LIST.**

12          Title V (21 U.S.C. 351 et seq.) is amended by insert-  
13          ing after section 506C the following new section:

14 **“SEC. 506D. DRUG SHORTAGE LIST.**

15          “(a) ESTABLISHMENT.—The Secretary shall main-  
16          tain an up-to-date list of drugs that are determined by  
17          the Secretary to be in shortage in the United States.

18          “(b) CONTENTS.—For each drug on such list, the  
19          Secretary shall include the following information:

20                  “(1) The name of the drug in shortage.

21                  “(2) The name of each manufacturer of such  
22          drug.

23                  “(3) The reason for the shortage, as determined  
24          by the Secretary, selecting from the following cat-  
25          egories:

1           “(A) Requirements related to complying  
2           with good manufacturing practices.

3           “(B) Regulatory delay.

4           “(C) Shortage of an active ingredient.

5           “(D) Shortage of an inactive ingredient  
6           component.

7           “(E) Discontinuation of the manufacture  
8           of the drug.

9           “(F) Delay in shipping of the drug.

10          “(G) Demand increase for the drug.

11          “(4) The estimated duration of the shortage as  
12          determined by the Secretary.

13          “(c) PUBLIC AVAILABILITY.—

14               “(1) IN GENERAL.—Subject to paragraphs (2)  
15               and (3), the Secretary shall make the information in  
16               such list publicly available.

17               “(2) TRADE SECRETS AND CONFIDENTIAL IN-  
18               FORMATION.—Nothing in this section alters or  
19               amends section 1905 of title 18, United States Code,  
20               or section 552(b)(4) of title 5 of such Code.

21               “(3) PUBLIC HEALTH EXCEPTION.—The Sec-  
22               retary may choose not to make information collected  
23               under this section publicly available under paragraph  
24               (1) if the Secretary determines that disclosure of  
25               such information would adversely affect the public

1 health (such as by increasing the possibility of  
2 hoarding or other disruption of the availability of  
3 drug products to patients).”.

4 **SEC. 903. QUOTAS APPLICABLE TO DRUGS IN SHORTAGE.**

5 Section 306 of the Controlled Substances Act (21  
6 U.S.C. 826) is amended by adding at the end the fol-  
7 lowing:

8 “(h)(1) Not later than 30 days after the receipt of  
9 a request described in paragraph (2), the Attorney Gen-  
10 eral shall—

11 “(A) complete review of such request; and

12 “(B)(i) as necessary to address a shortage of a  
13 controlled substance, increase the aggregate and in-  
14 dividual production quotas under this section appli-  
15 cable to such controlled substance and any ingre-  
16 dient therein to the level requested; or

17 “(ii) if the Attorney General determines that  
18 the level requested is not necessary to address a  
19 shortage of a controlled substance, the Attorney  
20 General shall provide a written response detailing  
21 the basis for the Attorney General’s determination.  
22 The Secretary shall make the written response pro-  
23 vided under subparagraph (B)(ii) available to the  
24 public on the Web site of the Food and Drug Ad-  
25 ministration.

1 “(2) A request is described in this paragraph if—

2 “(A) the request pertains to a controlled sub-  
3 stance on the list of drugs in shortage maintained  
4 under section 506D of the Federal Food, Drug, and  
5 Cosmetic Act;

6 “(B) the request is submitted by the manufac-  
7 turer of the controlled substance; and

8 “(C) the controlled substance is in schedule  
9 II.”.

10 **SEC. 904. EXPEDITED REVIEW OF MAJOR MANUFACTURING**  
11 **CHANGES FOR POTENTIAL AND VERIFIED**  
12 **SHORTAGES OF DRUGS THAT ARE LIFE-SUP-**  
13 **PORTING, LIFE-SUSTAINING, OR INTENDED**  
14 **FOR USE IN THE PREVENTION OF A DEBILI-**  
15 **TATING DISEASE OR CONDITION.**

16 Subsection (c) of section 506A (21 U.S.C. 356a) is  
17 amended by adding at the end the following new para-  
18 graph:

19 “(3) CHANGES ADDRESSING A DRUG SHORT-  
20 AGE.—

21 “(A) CERTIFICATION.—

22 “(i) DESCRIPTION.—A certification is  
23 described in this subparagraph if the man-  
24 ufacturer, having notified the Secretary of  
25 an interruption or discontinuance of a drug

1 in accordance with Section 506C, certifies  
2 (in such certification) that the major man-  
3 ufacturing change for which approval is  
4 being sought may prevent or alleviate a  
5 discontinuance or interruption of such  
6 drug.

7 “(ii) BAD FAITH EXCEPTION.—Sub-  
8 paragraphs (B) and (C) do not apply in  
9 the case of a certification which the Sec-  
10 retary determines to be made in bad faith.

11 “(B) EXPEDITED REVIEW.—If a certifi-  
12 cation described in subparagraph (A) is sub-  
13 mitted in connection with a supplemental appli-  
14 cation for a major manufacturing change, the  
15 Secretary shall—

16 “(i) expedite any technical review or  
17 inspection necessary for consideration of  
18 the supplemental application;

19 “(ii) provide any technical assistance  
20 necessary to facilitate approval of the sup-  
21 plemental application; and

22 “(iii) not later than 60 days after re-  
23 ceipt of the certification, complete review  
24 of the supplemental application.”.

1 **SEC. 905. STUDY ON DRUG SHORTAGES.**

2 (a) STUDY.—The Comptroller General of the United  
3 States shall conduct a study to examine the cause of drug  
4 shortages and formulate recommendations on how to pre-  
5 vent or alleviate such shortages.

6 (b) CONSIDERATION.—In conducting the study under  
7 this section, the Comptroller General shall consider the  
8 following questions:

9 (1) What are the dominant characteristics of  
10 drugs that have gone into actual shortage over the  
11 preceding three years?

12 (2) Are there systemic high-risk factors (such  
13 as drug pricing structure, including Federal reim-  
14 bursements, or the number of manufacturers pro-  
15 ducing a drug product) that have led to the con-  
16 centration of drug shortages in certain drug prod-  
17 ucts that have made such products vulnerable to  
18 drug shortages?

19 (3) Is there a reason why drug shortages have  
20 occurred primarily in the sterile injectable market  
21 and in certain therapeutic areas?

22 (4) How have regulations, guidance documents,  
23 regulatory practices, and other actions of Federal  
24 departments and agencies (including the effective-  
25 ness of interagency and intraagency coordination,

1 communication, strategic planning, and decision-  
2 making) affected drug shortages?

3 (5) How does hoarding affect drug shortages?

4 (6) How would incentives alleviate or prevent  
5 drug shortages?

6 (7) How are healthcare providers, including  
7 hospitals and physicians responding to drug short-  
8 ages, to what extent are such providers able to ad-  
9 just care effectively to compensate for such short-  
10 ages, and what impediments exist that hinder pro-  
11 vider ability to adjust to such shortages?

12 (c) CONSULTATION WITH STAKEHOLDERS.—In con-  
13 ducting the study under this section, the Comptroller Gen-  
14 eral shall consult with relevant stakeholders, including  
15 physicians, pharmacists, hospitals, patients, drug manu-  
16 facturers, and other health providers.

17 (d) REPORT.—Note later than 18 months after the  
18 date of the enactment of this Act, the Comptroller General  
19 shall submit a report to the Committee on Energy and  
20 Commerce of the House of Representatives and the Com-  
21 mittee on Health, Education, Labor, and Pensions of the  
22 Senate on the results of the study under this section.

23 **SEC. 906. ANNUAL REPORT ON DRUG SHORTAGES.**

24 Not later than 18 months after the date of the enact-  
25 ment of this Act, and annually thereafter, the Secretary



1 of Health and Human Services shall submit to the Com-  
2 mittee on Energy and Commerce of the House of Rep-  
3 resentatives and the Committee on Health, Education,  
4 Labor, and Pensions of the Senate a report on drug short-  
5 ages that—

6           (1) describes the communication between the  
7       field investigators of the Food and Drug Administra-  
8       tion and the staff of the Center for Drug Evaluation  
9       and Research’s Office of Compliance and Drug  
10      Shortage Program, including the Food and Drug  
11      Administration’s procedures for enabling and ensur-  
12      ing such communication;

13          (2) describes the Food and Drug Administra-  
14      tion’s efforts to expedite the review of new manufac-  
15      turing sites, new suppliers, and specification changes  
16      to prevent or alleviate a drug shortage;

17          (3) describes the coordination between the Food  
18      and Drug Administration and the Drug Enforce-  
19      ment Administration on efforts to prevent or allevi-  
20      ate drug shortages;

21          (4) identifies the number of, and describes the  
22      instances in which the Food and Drug Administra-  
23      tion exercised regulatory flexibility and discretion to  
24      prevent or alleviate a drug shortage;

1           (5) identifies the number of instances in which  
2           the Food and Drug Administration asked firms to  
3           increase production to prevent or alleviate a short-  
4           age;

5           (6) identifies the number of notifications sub-  
6           mitted to the Secretary under section 506C of the  
7           Federal Food, Drug, and Cosmetic Act, as amended  
8           by section 901 of this Act, including the percentage  
9           of such notifications for a drug that is a sterile  
10          injectable;

11          (7) describes the Food and Drug Administra-  
12          tion's implementation of section 506D of the Fed-  
13          eral Food, Drug, and Cosmetic Act (relating to a  
14          drug shortage list), as added by section 902 of this  
15          Act, and identifies—

16                (A) the name of each drug on the list  
17                under such section 506D at any point during  
18                the period covered by the report;

19                (B) the name of each manufacturer of  
20                each such drug;

21                (C) the reason for the shortage of each  
22                such drug; and

23                (D) the anticipated or, if known, actual  
24                duration of the shortage of each such drug;

1           (8) identifies whether, and how, the Food and  
2       Drug Administration expedited the review of regu-  
3       latory submissions to prevent or alleviate shortages,  
4       including how the Administration utilized the au-  
5       thority in section 506A(c)(3) of the Federal Food,  
6       Drug, and Cosmetic Act, as added by section 904 of  
7       this Act;

8           (9) identifies the number of certifications sub-  
9       mitted under such section 506A(c)(3) and, for each  
10      such certification, whether the Food and Drug Ad-  
11      ministration completed expedited review within 60  
12      days as required by subparagraph (B) of such sec-  
13      tion 506A(c)(3);

14          (10) describes the Secretary's public engage-  
15      ment on drug shortages with stakeholders, including  
16      physicians, pharmacists, patients, hospitals, drug  
17      manufacturers, and other health providers; and

18          (11) contains the Secretary's plan for address-  
19      ing drug shortages in the upcoming year, including  
20      with respect to the issues described in paragraphs  
21      (1) through (10).

22   **SEC. 907. ATTORNEY GENERAL REPORT ON DRUG SHORT-**  
23                   **AGES.**

24      Not later than 6 months after the date of the enact-  
25      ment of this Act, and annually thereafter, the Attorney

1 General shall submit to the Committee on Energy and  
2 Commerce of the House of Representatives and the Com-  
3 mittee on the Judiciary of the Senate a report on drug  
4 shortages that—

5 (1) identifies the number of requests received  
6 under section 306(h) of the Controlled Substances  
7 Act (as added by section 903 of this Act), the aver-  
8 age review time for such requests, the number of re-  
9 quests granted and denied under such section, and,  
10 for each of the requests denied under such section,  
11 the basis for such denial;

12 (2) describes the coordination between the Drug  
13 Enforcement Administration and Food and Drug  
14 Administration on efforts to prevent or alleviate  
15 drug shortages; and

16 (3) identifies drugs containing a controlled sub-  
17 stance subject to section 306 of the Controlled Sub-  
18 stances Act when such a drug is determined by the  
19 Secretary of Health and Human Services to be in  
20 shortage.

21 **SEC. 908. HOSPITAL REPACKAGING OF DRUGS IN SHORT-**  
22 **AGE.**

23 Chapter V (21 U.S.C. 351 et seq.), as amended by  
24 section 902 of this Act, is further amended by inserting  
25 after section 506D the following:

1 **“SEC. 506E. HOSPITAL REPACKAGING OF DRUGS IN SHORT-**  
2 **AGE.**

3 “(a) DEFINITIONS.—In this section:

4 “(1) DRUG.—The term ‘drug’ excludes any con-  
5 trolled substance (as such term is defined in section  
6 102 of the Controlled Substances Act).

7 “(2) HEALTH SYSTEM.—The term ‘health sys-  
8 tem’ means a collection of hospitals that are owned  
9 and operated by the same entity and that share ac-  
10 cess to databases with drug order information for  
11 their patients.

12 “(3) REPACKAGE.—For the purposes of this  
13 section only, the term ‘repackage’, with respect to a  
14 drug, means to divide the volume of a drug into  
15 smaller amounts in order to—

16 “(A) extend the supply of a drug in re-  
17 sponse to the placement of the drug on a drug  
18 shortage list described in subsection (b); and

19 “(B) facilitate access to the drug by hos-  
20 pitals within the same health system.

21 “(b) EXCLUSION FROM REGISTRATION.—Notwith-  
22 standing any other provision of this Act, a hospital shall  
23 not be considered an establishment for which registration  
24 is required under section 510 solely because it repackages  
25 a drug and transfers it to another hospital within the same

1 health system in accordance with the conditions in sub-  
2 section (c)—

3 “(1) during any period in which the drug is list-  
4 ed on the Drug Shortage List of the Food and Drug  
5 Administration; or

6 “(2) during the 60-day period following any pe-  
7 riod described in paragraph (1).

8 “(c) CONDITIONS.—Subsection (b) shall only apply to  
9 a hospital, with respect to the repackaging of a drug for  
10 transfers to another hospital within the same health sys-  
11 tem, if the following conditions are met:

12 “(1) DRUG FOR INTRASYSTEM USE ONLY.—In  
13 no case may a drug that has been repackaged in ac-  
14 cordance with this section be sold or otherwise dis-  
15 tributed by the health system or a hospital within  
16 the system to an entity or individual that is not a  
17 hospital within such health system.

18 “(2) COMPLIANCE WITH STATE RULES.—Re-  
19 packaging of a drug under this section shall be done  
20 in compliance with applicable State requirements in  
21 which the health system is located.

22 “(d) TERMINATION.—This section shall not apply on  
23 or after the date on which the Secretary issues final guid-  
24 ance that clarifies the policy of the Food and Drug Admin-  
25 istration regarding hospital pharmacies repackaging and

- 1 safely transferring repackaged drugs to other hospitals
- 2 within the same health system during a drug shortage.”.

Union Calendar No. 348

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> Session

**H. R. 5651**

[Report No. 112-495]

**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs and for medical devices, to establish user-fee programs for generic drugs and biosimilars, and for other purposes.

MAY 25, 2012

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed